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Estimating the Demand, Supply, and National Costs of HIV Testing

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ESTIMATING THE DEMAND, SUPPLY, AND NATIONAL COSTS OF HIV TESTING

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ESTIMATING THE DEMAND, SUPPLY, AND NATIONAL COSTS OF HIV TESTING

INTRODUCTION

This protocol is the fifth of six research protocols funded by the NCHSR. The NCHSR is developing a research agenda to study the economic cost of AIDS and HIV-related infection. To achieve this goal the NCHSR has directed that research protocols be developed in the following six areas:

* Estimation of the direct costs of providing medical, social and support services to persons with AIDS and ARC

* Assessment of the cost-effectiveness of different treatment modalities

* Assessment of the cost-effectiveness of different ways of organizing and delivering services

* Comparisons of the cost of AIDS with the cost of other illnesses

* Estimation of the supply and demand for HIV testing services and calculations of the national cost of HIV testing

* Projection of the health manpower requirements associated with treating AIDS patients and patients with HIV-related infection and estimation of the costs associated with training the necessary manpower

This protocol develops a research project to estimate the supply of and demand for HIV testing services and to develop national estimates of the cost of HIV testing. This introduction describes the importance of the protocol and discusses the major policy questions to be addressed in the proposed research.

Importance of this Protocol

The rising number of AIDS cases in the United States combined with the high probability that HIV infection will eventually lead to AIDS has resulted in increased emphasis on HIV screening and testing to identify the population at highest risk of acquiring AIDS. HIV testing, particularly mandatory testing and reporting of HIV-positive persons is an extremely controversial topic. The desire to balance individual freedoms and protect persons who are HIV positive from discrimination, plus the desire of public health officials to calculate the magnitude of HIV infection have made the design and implementation of HIV testing and screening programs critical to the understanding of the AIDS epidemic. In addition, as more efficacious treatments for HIV-related infections and AIDS are developed and started early in the course of infection, and if HIV infection increasingly spreads to other populations, the need to devote additional resources to HIV testing will increase.

Importance of HIV Testing

HIV testing programs are important for four primary reasons. First, information on the number of HIV-positive persons can be used to project the future number of AIDS cases that the nation can expect. While there is no agreement on the current number of infected persons in the United States, most experts agree that there is a high probability that HIV infection will eventually result in AIDS, and most of those who are infected with the HIV virus do not know it. Consequently, HIV testing of the population is critical to predict the future course of the epidemic.

A large share of the cost burden for treating AIDS and HIV-related infection is government financed. The current high cost of treating AIDS causes many individuals to spend down to Medicaid eligibility. In addition, if life expectancy of AIDS patients increases beyond 2 years, there will be an increase in Medicare payments resulting from the categorization of AIDS as a presumptive disability. Also, private insurers are beginning to test applicants for individual insurance policies and deny coverage to those who are seropositive. Many of these individuals will eventually rely on the government sector to finance some of their care. Information on the incidence of HIV infection in different population groups can be used to predict the future financial impact of AIDS and HIV-related infection on the public sector.

Third, HIV testing is an important diagnostic tool. Because most people with HIV infection are asymptomatic, clinical presentation is insufficient for disease identification. In the past there was little treatment offered to those who tested HIV positive. In part, this was due to the toxicity of available treatments, and the estimated probabilities that seropositive individuals would progress to AIDS was less than 50 percent. However, as our knowledge of disease progression increases, and as treatment regimens are started earlier in the course of infection, it is important that those who are HIV positive be identified and placed in treatment programs as rapidly as possible.

Finally, HIV testing/screening has an educational component to it. Individuals who are tested often receive pretest and posttest counseling as to methods of HIV transmission and risk factors associated with acquiring HIV infection. It is hoped that this counseling process in combination with learning their HIV status will help individuals modify their risky behavior.

Importance of Measuring HIV Testing Costs

Estimation of HIV testing costs is important for four major reasons: 1) accountability, 2) resource allocation, 3) understanding the distribution of the cost burden, and 4) developing the cost component for future cost/benefit analyses. The Centers for Disease Control (CDC) currently fund approximately 1,100 public counseling and testing sites. Given the magnitude of the public sector funds involved, it is important for the government to account for its expenditures, and ensure that funds are spent to achieve the ends to which they were directed.

Efficient resource allocation requires that funds be distributed across activities so as to maximize the benefits to society. Allocations of funds to HIV testing must be balanced against funds for treatment and research as well as other government health and nonhealth activities. Without data on HIV testing costs, efficiency in resource allocation cannot be achieved.

Government plays an important role in financing both the care of AIDS patients and the costs of HIV testing. Future government financial liability for treating AIDS patients will depend on the number and characteristics of the population that is currently seropositive. HIV testing of different population groups is crucial if the government is to be able to estimate the size and distribution of future treatment costs.

Finally, information on HIV testing costs can be used as the basis for evaluating the cost-effectiveness of testing in different population groups. This information can be used to direct public decision-making with respect to HIV testing policy.

Major Policy Questions

This protocol addresses four major policy questions:

* What are the determinants of the supply and average costs of HIV testing services?

* What are the determinants of the demand for HIV testing services?

* What are the current national costs of HIV testing?

* What are the projected costs of HIV testing under different scenarios?

This research protocol, which outlines the research steps necessary to develop answers to the above questions, is divided into seven section:

Section I discusses the HIV tests currently in existence and the costs and characteristics of each test. The section also provides a description of emerging tests that may be implemented in the future and provides an overview of the organization of the supply of testing services.

Section II describes the available data on utilization of testing services and cost of testing services in three population groups. It separately examines the populations for which the government has mandated testing, the population receiving tests that other third parties have initiated, and the population that voluntarily elects to be tested.

Section III discusses the methodological issues associated with estimating the costs of testing including: defining costs, describing the components of costs, and measuring costs. It describes how other researchers have calculated costs for other diagnostic tests and concludes with a discussion of the determinants of average testing costs.

Section IV assesses alternative approaches to estimating testing costs and provides a recommended approach to cost estimation. The section evaluates existing databases, proposes a strategy for data collection, and designs an empirical model for cost estimation.

Section V develops an empirical model for estimating individual demand for HIV testing. It evaluates alternative options for demand estimation, describes existing databases and data gaps, and recommends a strategy for data collection. The section concludes with the specification of an empirical model of demand.

Section VI develops a methodology for estimating the national cost of HIV testing. Using the results of the supply and demand models developed in sections IV and V, it describes how HIV testing costs can be simulated under different assumptions regarding the scope of mandated testing, the size and characteristics of the population, and the characteristics of the different test protocols.

Section VII presents recommendations for implementing the studies designed in the protocol. It describes the research tasks involved in producing the study, proposes a time schedule for the study, and estimates resource requirements for implementing the protocol.

I. DESCRIPTION OF CURRENT PROCESS FOR DETECTING HIV INFECTION

A. Introduction

Detecting HIV infection in individuals or populations can be performed in a variety of different ways. The cost of detecting HIV infection will vary considerably depending on the protocol used to identify infection as well as other factors, such as the volume of tests performed, the risk characteristics of the individuals being tested, state regulations regarding training of lab personnel, and lab performance standards. In addition, new tests are constantly being developed that improve sensitivity and specificity, and may lower cost.

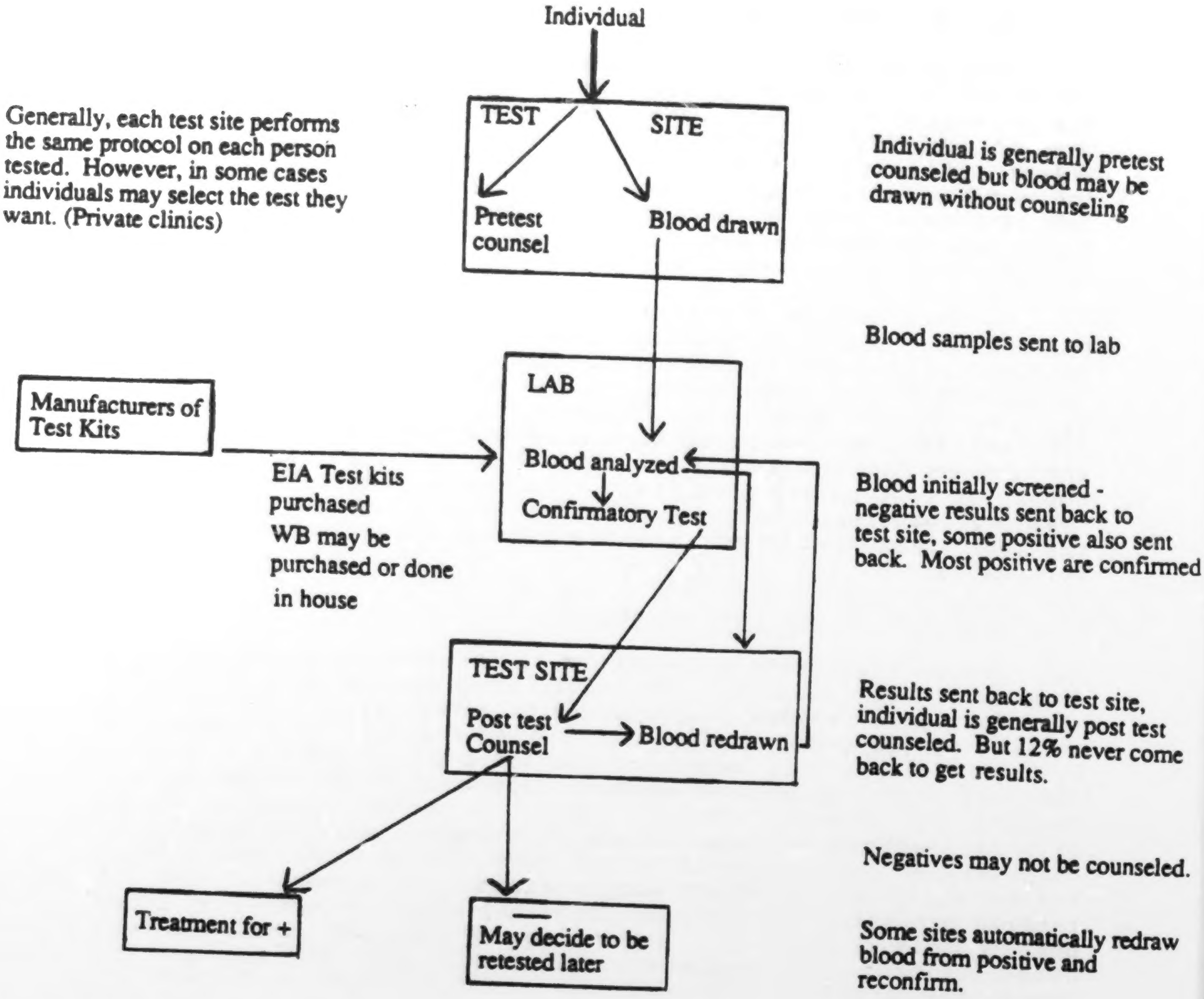
In this section, a description of the current process of testing for HIV infection is provided. An overview of the testing process and a brief technical description of HIV testing is presented (SEE Appendix A for a comprehensive discussion of HIV testing). Then, the different types of tests currently available and the emerging trends in HIV testing are discussed. The chapter ends with a discussion of the organization of the supply of testing services that includes the relationship between test kit manufacturers, laboratories performing the tests, and the test sites that provide counseling and draw the blood samples for analysis.

B. Overview of the Testing Process

Figure 1 presents an overview of the testing process in the form of a flow diagram. The first step of the process is for the individual to come in contact with a test site. This initial contact may be voluntarily initiated by the individual, mandated by law (military), or required by a third party (health insurer). The test site may be an alternate test site (ATS) funded by the Centers for Disease Control (CDC), or other publicly funded clinics (methadone, tuberculosis, prenatal), private physician, hospital, or other type of site. At the site, individuals being tested will have a blood sample drawn. They may or may not receive pretest counseling at the site, although most test sites perform this counseling. However, many hospitals draw and test blood without the patient's knowledge and may provide no counseling at all.

Once the blood is drawn, it will be sent to a lab for analysis. Generally, each test site uses the same lab testing protocol on each person tested. However, in some instances the individuals themselves will demand a certain test. For example, some individuals may specifically request an antigen test rather than an antibody test. While the test protocol may dictate the

Figure 1. Overview of the HIV testing process


Individual
TEST SITE
Pretest counsel
Blood drawn
LAB
Manufacturers of Test Kits
EIA Test kits purchased
WB may be purchased or done in house
Blood analyzed
Confirmatory Test
TEST SITE
Post test Counsel
Blood redrawn
Treatment for +
May decide to be retested later

Generally, each test site performs the same protocol on each person tested. However, in some cases individuals may select the test they want. (Private clinics)

Individual is generally pretest counseled but blood may be drawn without counseling

Blood samples sent to lab

Blood initially screened - negative results sent back to test site, some positive also sent back. Most positive are confirmed

Results sent back to test site, individual is generally post test counseled. But 12% never come back to get results.

Negatives may not be counseled.

Some sites automatically redraw blood from positive and reconfirm.

type of tests to be performed, the lab may use discretion with respect to which manufacturer's tests it will use in performing the testing (there are a number of manufacturers of EIA tests), or whether it will develop its own in house test (currently there is only one manufacturer of Western blot tests).

Different test sites will require different protocols. The protocols may vary both in the types of test used and in the sensitivity and specificity levels that are acceptable. Some test sites, such as blood banks, will demand one level of sensitivity and specificity while another site, such as an ATS, will have a different set of requirements.

Most of the test protocols require that a blood sample, if initially testing positive for HIV infection, be confirmed using additional tests. However, if individuals use private test sites, it may be up to the individual being tested as to whether a confirmatory test is performed.

Figure 1 has separated the test kit manufacturers from the labs. However, it is possible for the manufacturers to perform the testing themselves.

Once the blood has been analyzed, the results will be returned to the test site. Individuals will generally be post-test counseled. (If the test was performed in the hospital without the patient's consent, patients may never receive counseling or results. In some instances, such as in the military, a second blood sample will be drawn and retested if the first sample is positive.

Those individuals who test positive for HIV infection will generally be counseled as to treatment options and may be directed to a specific program. Those who test negative will generally also receive counseling regarding risk reduction and may get retested at a later date. Some fraction of the population that is tested will never return to get the results.

C. Distinction Between Testing and Screening and Between Diagnosis and Screening

The Institute of Medicine (IOM) recognizes a distinction between HIV testing and screening. "Screening" implies offering a test to a whole population to determine the members' antibody status. "Testing" implies offering the test to an individual based on his or her request or that of a provider. The major difference is whether the technique is individual or population based. For the sake of discussion in this protocol, "testing" applies to both population and individual-based HIV detection programs.

In addition to the screening/testing distinction, a distinction should be made between diagnosis and screening. Diagnosis is defined as the identification of disease or the act of recognizing the presence of disease (DeGowin & DeGowin, 1969). Screening is defined as "the presumptive identification of unrecognized disease or defection by the application of tests, examinations, or other procedures that can be applied rapidly (U.S. Commission of Chronic Illness, 1957)."

Frame and Carlson (1975), in the course of reviewing periodic health screening programs, established six criteria that they deem necessary to justify screening for a given disease:

1. The disease must have a significant effect on quality or quantity of life.
2. Acceptable methods of treatment must be available.
3. The disease must have an asymptomatic period during which detection and treatment significantly reduce morbidity and mortality.
4. Treatment in the asymptomatic phase must yield a therapeutic result superior to that obtained by delaying treatment until symptoms appear.
5. Tests must be available at reasonable cost to detect the condition in the asymptomatic period.
6. The incidence of the condition must be sufficient to justify the cost of screening.

However, these criteria do not address the issue of transmissability and the use of screening to identify individuals with infectious conditions. A seventh criteria can be added to this list--the screening identifies transmissible illness and is performed in a setting in which the process of identification promotes prevention of transmission. The efficacy of HIV screening in the prevention of HIV transmission is a controversial topic. Evidence is mixed on whether screening programs promote behavior change that reduces HIV transmission.

D. HIV Testing As Diagnostic Tool Versus Treatment

The costs related to providing a diagnostic test must be distinguished from those of providing care to the patients with the disease that the test detects. Diagnostic testing costs include those produced by obtaining a specimen, processing the specimen, performing the diagnostic test (includes reagents, equipment, and labor), similar costs produced by other confirmatory diagnostic tests, interpretation of the test results, cost of informing and counseling the test recipient about the test procedure, the limitations of the test and the meaning of the test results, costs produced by record keeping, maintenance of confidentiality, and costs generated by inaccuracy in the testing procedure (laboratory error and false test results).

The costs related to the disease, such as the costs of treatment, loss of function due to the disease, and emotional distress resulting from the diagnosis of disease, must be distinguished from the costs generated by use of the diagnostic instrument. For example, the costs associated with use of chest radiography in the diagnosis of lung cancer include cost of the x-ray and counseling the recipient regarding the utility and accuracy of the procedure in screening for cancer. The cost of treatment for lung cancer, even if the x-ray permitted an early discovery of disease, is not a result of the diagnostic test but of the cancer itself. The cost of any counseling provided for the lung cancer patient because of emotional discord produced by the diagnosis of cancer is attributable to the cancer rather than the chest x-ray that identified the disease.

By analogy, in the case of HIV, the costs generated by testing for HIV can be distinguished from costs of HIV-related medical and psychological problems. Hessol (1988) and colleagues recently reported an estimate that almost 50 percent of those infected with HIV will develop AIDS within 9 years. With longer periods of observation, the incidence of AIDS among individuals who are infected with HIV is likely to continue to increase. Thus, the diagnosis of HIV infection may portend a future AIDS case. In the setting of a disease with such a poor prognosis and limited available treatment, it is tempting to consider costs related to the early treatment and psychological needs of patients to be generated by HIV diagnostic tests. However, as in the field of cancer screening, diagnostic procedures that detect HIV infection must be separated from the process of treating the infection.

The costs of HIV testing programs is generated by:

- obtaining a specimen (usually blood)
- processing the specimen
- performing the test
- informing and counseling the test recipient about the reliability, utility, and meaning of the test results
- maintenance of test result records in a useful and private form
- counseling and care of individuals who receive erroneous test results

Not included in costs generated by HIV testing are:

- counseling regarding treatment and prognosis of HIV infection
- treatment costs, including the treatment of early HIV infection

These are costs that arise as a result of the disease and would arise regardless of the method of testing used to detect the disease. In conducting this protocol, the definition of testing costs is defined above.

E. Technical Description of Detection of the HIV Infection

This section presents a summary discussion of the technical aspects of detection of HIV infection, including the mechanisms of infection and the diagnostic tests that detect infection (see Appendix A for a detailed discussion on this subject). The technical discussion has been placed in the Appendix to facilitate review of the protocol. However, the Appendix provides information that may be useful to the future contractor.

HIV infection occurs after intimate contact between a susceptible (uninfected) person and infectious material. Intimate contact includes exposure of mucous membrane tissue, such as the vagina, rectum, or urethra to, or injection of, materials that contain HIV. Infection with HIV does not follow every intimate exposure; a fraction of exposures actually result in HIV infection.

1. Testing for HIV Infection

The presence of infection can be determined several ways. Infection may lead to characteristic symptoms of disease. Some diseases (such as chickenpox) are most commonly and accurately diagnosed on the basis of clinical presentation. Other illnesses cannot be accurately diagnosed on the basis of clinical manifestations (such as breast cancer), and a diagnostic test rather than clinical presentation is used to determine the diagnosis.

Sensitivity, or the probability that a diseased individual tests positive, is one way to assess accuracy of a diagnostic test (Ingelfinger, 1983). Sensitivity is a conditional probability. It is defined as (T+/D+), where T+ is the number of positive diagnostic test results, and D+ is the number of individuals with disease. A sensitive test is more apt to detect disease than an insensitive one. A sensitive test will not miss cases of HIV infection.

A second measure of test accuracy is specificity, or the probability that an undiseased individual tests negative (Ingelfinger, 1983). Specificity is defined as (T-/D-), where T- is the number of negative test results, and D- is the number of individuals in the study population without disease. A specific test is less likely to falsely indicate disease than a nonspecific specific one. A specific test will not find HIV infection when it is not really present.

The sensitivity and specificity are characteristics of a given diagnostic test, they do not depend on the probability of disease within the population being tested.

By contrast, the positive predictive value of a test is influenced by the frequency of a given disease in the test population. Positive predictive value is defined by both the accuracy of a diagnostic test and the frequency of disease. The positive predictive value of a test is the proportion of positive tests that are associated with disease. Likewise the negative predictive value of a diagnostic test reflects both the accuracy of a test and the frequency of disease. The negative predictive value is defined as the proportion of negative tests that are associated with the absence of disease. In HIV testing, the positive predictive value of a test, or the chances that a positive test is not false, is much higher among persons in high-risk groups, such as homosexual men, than persons in low-risk groups (blood donors). A positive test in a heterosexual female blood donor with no other risk factors is more apt to be a false positive than a true positive. Table 1 shows the relationship between the predictive value of a positive result and the underlying disease prevalence in the population.

Diagnostic tests for infections include culture methods, methods to detect host response to infection, and newer methods that identify the DNA or gene products of microorganisms in host tissue. All of these approaches have been applied to the diagnosis of HIV infection, and a number of reliable and accurate tests are available. New types of HIV diagnostic tests are being introduced at a very rapid rate, which is producing difficulty for those who study issues related to HIV testing.

While all persons infected with HIV can potentially infect others, no test has been proven to predict the infectiousness of any given HIV-infected person, or whether their infectiousness changes over time.

2. Clinical Presentation as Method of Detecting HIV Infection

Clinical presentation would be a useful diagnostic method for detecting HIV infection only if new or recent infections could be reliably detected before onset of the asymptomatic

Table 1. Effect of prevalence on predictive value of a positive result

Prevalence (percent)	Predictive value of a positive result (percent)
0.1	2
1.0	16
2.0	28
5.0	50
10.0	68
50.0	95

phase. Onset of infection (acute infection) with HIV produces mononucleosis-like symptoms in up to 92 percent of cases identified in prospective studies of high-risk populations (Tindall, 1988; Cooper, 1985; Kessler, 1987). However, these symptoms are indicative of other diseases; therefore, clinical presentation is insufficient as a means of diagnosing HIV infection. Consequently, the specificity of clinical diagnosis of HIV infection is unacceptable; the value of clinical presentation as a means of identifying individuals with recent HIV infections is very limited.

3. Principal Diagnostic Tests Used to Detect HIV Infection

When infection occurs, HIV proliferates within and depletes host helper/inducer lymphocytes (a subset of white blood cells) (Bowen, 1985). Many different diagnostic tests are used to identify HIV infection. Those most frequently used are antibody detection (EIA, Western blot, radioimmunoprecipitation, and immunofluorescence), viral culture, antigen detection, and gene amplification. The following text summarizes these techniques and is followed by a brief description of the newer methods.

a. Direct culture tests

The process of performing a culture is lengthy, taking up to 10 days to complete, and it must be done in a facility that is certified to handle HIV (Jackson, 1987). A positive culture of HIV is positive proof of infection. However, because the proportion of white blood cells that are infected with HIV at any one time is small, sampling error can easily occur--blood drawn for HIV culture may not include the relatively rare HIV-infected cell.

HIV culture has been utilized in clinical studies to detect infection. The technique, however, is cumbersome and considered primarily a research tool. It is unlikely to be used as a mass screening test. Rather, it has been used as a gold standard due to its high specificity. Existing reports show that HIV culture can be relatively insensitive in certain laboratories. High degree of variability between laboratories in the sensitivity of HIV culture also limits the value of the technique in diagnostic testing. However, the sensitivity of the HIV culture appears to have increased with time, and the method may be used as a confirmatory test if future studies produce more consistent results.

b. Antigen detection

HIV antigens can be identified in blood and serum (a cell free or liquid component of blood). One technique for determining the presence of HIV antigens is the EIA (also called ELISA, enzyme immunoassay, enzyme-linked immunoassay, antigen capture assay, immunocapture assay, or solid-phase immunoassay), which is a version of the technique used to detect HIV antibodies.

Several manufacturers produce HIV EIA antigen detection kits, while many research laboratories use their own EIA tests. The EIA tests usually take about 4 hours, and cost is estimated at about $5.50 per test (personal communication with Coulter Corporation).

The presence of HIV antigens in the blood or serum is sufficient to diagnose HIV infection. HIV antigens can be found in blood shortly after infection when they are at their peak level, then, the level declines. The decline in antigen level corresponds to a rise in serum antibody. Thus, an antigen test is particularly useful immediately after suspected infection (such as following a needle stick), when antibody levels are insufficient to be detected by existing tests.

The following summary points can be drawn from existing studies:

- A positive antigen test (HIV antigen in blood) is often present early after HIV infection, before serum antibodies develop.
- A positive antigen test may recur late in the time-course of HIV infection.

* The recurrence of HIV antigen often coincides with a decrease in serum antibody levels.

* Some patients with a positive antigen test remain healthy for long periods of time.

* Many asymptomatic, ARC and AIDS patients have negative antigen tests.

* HIV antigen is not detected consistently prior to seroconversion.

* Medications may impair antigen detection.

These points demonstrate the limitations of antigen testing for the detection of HIV infection; sensitivity in the clinical setting is low, though specificity is greater than 99 percent (no false positive tests have been reported). While HIV antigen tests may be of limited value in detecting infection, they may have a role as indicators of disease progression, or in screening under special circumstances.

c. Detection of anti-HIV antibodies

Enzyme Immunoassay (EIA). The first method for the detection of antibodies to HIV was the EIA test reported by Sarngadharan in 1984. The test was designed as a tool for screening donated blood. In March 1985, the Food and Drug Administration (FDA) approved, for the screening of donated blood, EIA test kits manufactured by three laboratories (Abbott, Electro-Nucleonics, and Litton Bionetics).

The commercial EIA tests take up to 2 hours to run and require the use of a spectrophotometer. It is a large and expensive piece of equipment, which may make it unfeasible to perform the test in developing countries, physician offices, emergency rooms, and some other settings. The EIA is a relatively inexpensive test, however. Most kits cost less than $5.00 per test, though this cost may be significant in any setting in which large numbers of specimens are screened. Recently, several investigators have reported use of pooled sera to reduce the cost of screening large populations; this approach has the greatest potential in the screening of low prevalence populations (Hernandez-Avila, 1988; Quinn, 1988).

Positive EIA tests are highly predictive of illness related to HIV; however, insensitivity early in HIV infection is problematic. Serum antibodies to HIV are not present immediately after infection, which may be a cause of false-negative results, (inherent in the approach of testing by detection of antibodies).

False negative EIA tests have resulted in transmission of HIV to transfusion recipients. Table 2 presents data on the sensitivity and specificity of EIA tests currently on the market.

Despite the inherent limitations of sensitivity in early HIV infections, the EIA technique has been considered the backbone of HIV screening programs such as the blood bank program (Goedert, 1986). Whether a person tests positive or negative on the EIA test is subjective. Since the result of the EIA is determined by the amount of color change occurring in a clinical test, the cut-off level for deciding what constitutes a positive or negative test result rests with the lab performing the test. A low cut-off may be used in blood banking where a false negative test may result in the transmission of HIV to a blood recipient, while a high cut-off may be selected in a setting where the prevalence of HIV infection is expected to be relatively low and the outcome of a false positive test would be adverse (in prenatal screening of low risk women).

The impact of false positive EIA results varies with the prevalence of true HIV infection in the population to be tested. The prevalence of HIV infection in the general population, such as among blood donors, means that the majority of positive tests will be false even though the accuracy of EIA tests is very high and compares favorably with many other diagnostic tests. Some researchers have thus questioned the wisdom of applying the EIA as a tool for screening very low prevalence populations (Meyer, 1987).

In summary, the EIA test is:

- very sensitive and specific compared with other diagnostic tests,
- inexpensive, simple to perform, and rapid compared with other HIV diagnostic tests,
- relatively insensitive in early infection, as is any test that detects antibody to HIV,
- less sensitive in very late infection than it is during the asymptomatic phase,
- by far the most common test used for the detection of HIV infection,
- Modifiable and may be improved in future test kits.

The incidence of false positive EIA tests continues to be unacceptably high, particularly in very low prevalence populations. Continued HIV diagnostic testing of these populations is mandated by the needs of the blood banking industry, the policy of the US military and the personal choices of many individuals who appear to be at low risk for HIV infection. Thus, most positive EIA tests are confirmed by another test which employs different technology, such as the Western blot or the IFA.

Table 2. EIA tests: manufacturer and recent studies of accuracy

Manufacturer	Sensitivity	Specificity	Study
Abbott Abbott Laboratories	100.0	98.2	3
	99.6	74.6	4
	92.7	97.2	5
duPont duPont Company	100.0	88.0	4
Wellcome Wellcome Diagnostics	96.5	100.0	1
	100.0	99.9	3
	98.5	94.0	4
Litton Litton Diagnostics	98.8	98.9	3
	98.7	96.9	4
	90.0	99.3	5
Ortho Ortho Diagnostic System	96.5	99.6	1
ENI Electronucleonics	97.7	99.6	1
	98.8	99.3	3
	97.9	92.2	4
	78.1	99.3	5
Genetic Systems Genetic Systems Corp.	97.7	99.6	1
	99.8	99.8	2
Organon Teknika Organon Teknika Inc.	97.7	99.6	1
	98.2	99.7	3
	97.8	93.0	4
Pasteur Pasteur Diagnostics	99.4	99.7	3
	98.8	98.3	4
Sorin Sorin/Biomedica	100.0	70.0	4

Studies

1 - Ozanne and Fauvel, 1988
2 - Handsfield and others, 1987
3 - Reesink and others, 1986
4 - Deinhardt and others, 1987
5 - Taylor and others, 1988

Western Blot. The Western blot (WB) test has greater specificity than the EIA and is currently considered the "gold standard" confirmatory test for serum antibodies to HIV (Consortium for Retrovirus Serology Standardization, 1988). However, it is a cumbersome laboratory procedure, and currently only one manufacturer produces commercial reagents for the test, though many laboratories utilize their own WB procedures and reagents. This has resulted in a lack of standardization of testing procedures.

As with the EIA, the interpretation of a WB result is somewhat subjective. If stringent criteria are applied to the interpretation of WB tests, false negative results in early HIV infection will be inherent in the method. If stringent criteria are not applied to the interpretation of WB results, false positive readings can occur (Couroucè, 1986). The value of WB testing is a higher degree of specificity than that provided by EIA testing.

In general, the WB test is:

- subject to variability in interpretation,
- more specific than EIA if stringent criteria are applied to test interpretation,
- more sensitive than EIA in early HIV infection if stringent criteria are not applied,
- an expensive, time consuming and cumbersome laboratory procedure,
- the most commonly used confirmatory test,
- likely to become less variable with the development of new reagents and the standardization of the procedure.

Immunofluorescence (IFA). The IFA test is used as a confirmatory test for HIV infection. Like the EIA and the WB, the IFA detects the presence of anti-HIV antibodies. The technique involves microscopic examination of a serum specimen after laboratory preparation.

In general, IFA tests:

- have similar accuracy to Western blot,
- like WB, the procedure is variable,
- are slightly subjective--microscopy and determination of result must be standardized and performed by an experienced technician,
- are inexpensive once initial equipment is available, but relatively time consuming.

Currently, no IFA has been licensed for HIV testing, though many laboratories employ the test using reagents and procedures that may be unique to their setting. IFA methods are frequently employed in diagnostic laboratories in kit form; therefore, a commercial IFA kit for the detection of HIV infection is a likely development.

Radioimmunoassay. Radioimmunoassay (RIP, or RIPA) is also used as a confirmatory test for the detection of HIV infection. In brief, the RIPA procedure involves examining blood serum mixed with radioactively-marked HIV cells to determine the presence of HIV antibodies.

Briefly, the RIPA tests:

- are similar in accuracy to Western blot tests,
- are a common research tool,
- utilize radioactive reagents, and therefore are a troublesome test procedure,
- are not currently available as commercially prepared kits.

It is unlikely that RIPA will be used in large scale testing programs because other tests which have similar accuracy are available and RIPA tends to be more cumbersome. RIPA will continue to be a test that is used to assess the value of other tests.

Gene Amplification. Gene amplification or polymerase chain reaction (PCR) is a new "high tech" test which detects the presence of HIV DNA within host DNA. The technique has the theoretic advantage of identifying latent infection in individuals who do not make anti-HIV antibodies. PCR utilizes recombinant DNA technology and is currently in development as a commercial HIV diagnostic kit (Marx, 1988). The test takes about three hours to perform and currently costs about $135.00.

In review, PCR is:

- an expensive test which utilizes recombinant DNA technology,
- may detect latent HIV infection that other tests fail to detect, the clinical significance of which is not known,
- will soon be available in a commercially prepared kit,
- may be a useful confirmatory test or a new first-line screening test.

Additional diagnostic test methods. New test methods for the detection of HIV infection are listed in Table 3 with information on sensitivity and specificity. Many of the new tests are versions of tests that are currently available. The new tests can be evaluated by the kind of advantage they provide over previous tests and are examples of the kind of innovations that can occur using currently existing test technology:

Table 3. New HIV antibody diagnostic methods

1988 Reports	Sensitivity	Specificity	Comment
Competitive enzyme immunoassay			
Baillou	98.0	100.0	Compared with WB
Shih	100.0	NA	
Saxinger	100.0	100.0	New assay, more sensitive than WB confirmatory test
Paper spot			
Lillo	NA	NA	EIA, WB on paper spot, no venepuncture, home test potential
El Hamy	NA	NA	Same as above
Evengard	NA	NA	Same as above
Rubin	100.0	100.0	Same as above
Passive hemogglutination			
Weisner	100.0	NA	Simple, IgM included
Sher	NA	NA	Same as above
Lauwereys	100.0	94.0	Same as above
Takeda	100.0	100.0	Inhibition assay compared with EIA, WB-IgM included
Fiber optic test			
Giorgia	100.0	100.0	Very rapid compared with EIA
Particle agglutination			
Ismail	98.5	97.9	Simple
AGEN			
Kemp	NA	NA	Similar accuracy to EIA stated, rapid, inexpensive
Membrane binding			
Van de Perre	100.0	100.0	Compared with EIA rapid, easy

Simplification of laboratory technique and less equipment required

This group includes passive hemagglutination, particle agglutination, and AGEN tests. Some of these tests are less sensitive and specific than the currently used tests. These tests have the most utility in the developing world and settings in which a rapid and simple test is needed.

Simplification of specimen collection

Paper spot tests utilize EIA or WB methodology with blood specimens collected on filter paper from fingerprick rather than venopuncture, which is more cumbersome. The sensitivity and specificity of the EIA or WB is not altered. This method permits specimen collection in the home, without the assistance of medical professionals and simplifies collection from young children.

Rapid

The fiber optic test and membrane binding are both quick tests with high accuracy.

Greater accuracy.

Competitive enzyme immunoassays may be more sensitive and specific than other EIA tests and appear to be comparable to the Western blot in accuracy. The tests may have a role as confirmatory procedures (Dawson, 1988; Tedder, 1987).

Limitations of existing tests. Tests for the detection of HIV infection that are currently available have several inherent limitations. Lack of sensitivity early in infection and in terminal disease have been discussed in the preceding sections on detection of anti-HIV antibodies. Two additional situations in which currently licensed anti-HIV tests may be relatively insensitive are in the case of newborn infants and gamma globulin recipients.

Emerging trends in testing. New developments in HIV testing could permit in-home testing. Home testing could arise in two ways. Fingerstick specimens (obtained by sticking a finger with a sharp needle and absorbing the resultant drop of blood on a piece of paper) can be mailed to laboratories for testing. Another approach that would permit in-home testing is urine antigen testing, a possibility in the more distant future. In-home testing may offer privacy and freedom from coercion. However, the counseling of HIV test recipients, which is considered vital to any testing program, cannot be ensured with home tests. In addition, the accuracy of in-home tests is likely to be no better and potentially much worse than tests performed through the larger testing centers. The psychological implications of HIV testing, and the potential harm of testing without quality assurance or counseling must be weighed against the public interest and privacy of home testing.

Surrogate testing. Surrogate testing can be defined as the use of diagnostic procedures that detect conditions associated with either HIV infection (such as an impaired immune system) or risk factors for HIV infection (such as male homosexuality or intravenous drug abuse). Surrogate testing may be used instead of direct tests for HIV infection because of legal and ethical limitations on the use of the HIV tests. Surrogate tests take advantage of epidemiological information on conditions that are associated with AIDS or the behavioral risk factors for HIV infection.

Many tests can be used as surrogates: demographic information such as age, gender, and marital status, medical history, such as rectal gonorrhea or hepatitis related to IV drug abuse, and a long list of diagnostic tests that may detect conditions that are common among homosexual men, IV-drug abusers, hemophiliacs, and other high-risk individuals could all be possible surrogate measures. Some of these tests are listed in Table 4.

T-helper cell counts have received the most attention as surrogate tests. The T-helper cell is the type of lymphocyte (a white blood cell) that the AIDS virus destroys. As the duration of HIV infection increases, the average T-helper cell count decreases. Thus, T-helper cell counts are used as an indicator of HIV infection, despite the questionable accuracy of such a test for predicting HIV infection. Available data indicates that surrogate tests for HIV infection are:

- potentially large in number and varied, ranging from laboratory tests to questions about medical history or demographic information. Because of this, regulating the use of surrogate tests may be very difficult to achieve,
- much less sensitive and specific than the direct HIV tests; thus, use of such tests will produce many false positive and negative results.

F. Suppliers of Testing Services

The suppliers of testing can be divided into three groups: 1) manufacturers of the test kits, 2) laboratories that perform the testing, and 3) test sites where the samples are drawn. Although there is some overlap between these categories (manufacturers do some testing and testing sites may do their own lab work), they provide a framework for analyzing the impact of the organization of supply on the costs of testing.

Table 4. Potential surrogate tests of HIV infection

	Utility of tests	
Test	Pro	Con
T-helper cell count	Unusually low in AIDS and ARC Extremely low value fairly specific to HIV	Not a precise test; expensive; of limited value in early HIV infection
T-cell ratio	Similar to T-helper cell counts, the ratio decreases with duration of HIV infection	Not a precise test; expensive; limited value in early HIV infection
Hepatitis B core antibody	More prevalent in homosexual men and IV-drug users; precise; inexpensive	Nonspecific to HIV; prevalent in some ethnic and occupational groups
Syphilis test (VDRL, RPR)	More prevalent in homosexual men; inexpensive; rapid	Nonspecfic to HIV
Skin test for anergy	Absence of reactivity suggests immune dysfunction	Time consuming and difficult to perform; nonspecific to HIV

Little information is currently available on the resource costs of producing the tests or the price charged to different buyers. Both are likely to be influenced by the volume of tests produced, the market share of the company, and government regulation. Manufacturers may have contracts to be the sole provider of tests at a certain price, such as the contract between the American Red Cross and Abbot Laboratories to test donated blood. Although studies have compared different tests and some differences in performance have been found, tests are not currently different enough for one firm to have a monopoly on the market (Carlson, 1987). However, if a manufacturer developed a new, clearly superior test at a low price, a monopoly environment could develop, enabling the firm to maintain a price that is well above the cost of production.

1. Laboratories

The labs that conduct HIV testing can be divided into five types: 1) labs in blood collection centers, 2) hospital laboratories, 3) commercial laboratories, 4) state public health labs, and 5) private manufacturers' labs. Each of these will be discussed in turn.

a. Labs in blood or plasma collection centers

Blood collection centers perform HIV screening as part of their blood collection process. Screening is required at all primary sites of blood collection. There are approximately 2,500 blood collection centers in the U.S. Many of these are located in hospitals or other relatively small free-standing centers. About 75 percent of the 13 million units of blood collected per year in the nonprofit industry is collected by the American Red Cross and members of the Council of Community Blood Centers. The Red Cross is organized into 57 regions (largely along state lines) that operate 85 blood centers. The Council consists of 30 independent, nonprofit organizations that operate 45 blood collection facilities.

Plasma Collection Services are typically for-profit corporations that collect blood commercially and separate the plasma fractions and the various constituents for commercial sale. These sites disperse blood to blood banks and transfusion sites across the U.S. They are responsible for the testing and exclusion of infected units of blood from the system. Approximately 8 million units of blood are collected annually by plasma centers.

b. Commercial laboratories

Approximately 5,000 independent clinical laboratories in the U.S. are certified for participation in the Medicare and Medicaid programs. These labs constitute the core of the commercial lab industry, which may include as many as 10,000 firms. At present, only a fraction of these labs are believed to be conducting HIV testing. The larger national and regional firms generally perform such tests.

c. State public health laboratories

Testing for HIV is also being conducted in labs operated by the states. At present, the number of labs performing such work is unknown. It is believed that most states with significant numbers of AIDS cases operate such a service. Some states, such as New York, require that all HIV testing be performed by state labs.

d. Private manufacturers' laboratories

The manufacturers of EIA test kits have established labs as a courtesy to their customers to assist in the confirmation of HIV-positive samples. These labs are not licensed to perform diagnostic testing, and clinical information is not available from these labs.

2. Testing Sites

Testing for HIV is done at many different sites. The activities of most test sites include pretest and posttest counseling, drawing of blood to be sent to the lab for analysis, partner notification, and fulfilling reporting requirements. For the purpose of this discussion, the test sites have been divided into two groups: publicly funded sites and private sites.

a. Publicly funded test sites

In 1987, there were 1,100 public counseling and testing sites funded by the CDC and the states (Cahill, 1988). Public test sites include ATSs, hospitals, and health department clinics, including family planning, prenatal, sexually transmitted disease (STD), and drug abuse treatment clinics.

b. Private test sites

HIV testing is also done at private clinics and physicians' offices. It is not known how many private test sites are currently operating or how many tests they perform. Few states currently require reporting of private testing. A newspaper report (S.F. Chronicle, Nov. 22, 1987) estimates that 200 private clinics have been set up solely to provide HIV testing. An example given of a San Francisco clinic states that the patient is charged $39 for an EIA ($49 for same day results), $10 for a "Security Certificate" and an additional $140 for counseling if a confirmatory test is used. It is not known who the principal client group of the private test sites are, or whether expenses for such testing are paid out-of-pocket or by insurance.

II. DESCRIPTION OF CURRENT INFORMATION ON DEMAND, UTILIZATION, AND COST OF HIV TESTING SERVICES

A. Introduction

There are three components of demand for HIV testing: mandated demand, third-party initiated demand, and individually-initiated demand. Testing that is required by law is referred to as mandated. HIV testing may be mandated by the federal government or by state governments. Federal prisoners, military personnel, and immigrants are population groups for which the federal government has mandatory testing programs. Although no specific legislation has been passed mandating testing of donated blood, this practice has been universal since 1985 and will be considered part of mandatory testing. Some states have also mandated testing for prisoners, marriage license applicants, prostitutes, food handlers, and other population groups.

Third parties such as health insurers, life insurers, or health care providers are the second component of HIV testing demand. Although the individual may view a life insurer's decision to require HIV testing prior to offering insurance as a form of mandatory testing, the entity initiating the demand is not required to do so.

Individually initiated demand is that part of demand that arises out of individual utility maximization. It is completely voluntary. From the perspective of the individual, it is only this component of testing that actually represents demand.

In the first section of this chapter, a description of the mandatory HIV testing programs currently in existence is presented. For each population group, the policies regarding testing, examples of the type of testing protocols used, and the available epidemiologic and cost data are discussed. The following sections describe third party and individually-initiated testing.

B. Mandated Testing

1. Blood, Tissue, and Organ Donors

a. History of HIV testing

In March 1983, the US Food and Drug Administration (FDA) issued guidelines instructing blood collection centers to take steps to exclude members of high-risk groups from donating blood (FDA, 1983). Since 1985, the screening of blood and blood products for HIV infection has been a universal practice. Approximately 10 million blood donations are made annually (Eisenstaedt and Getzen, 1988). Although approximately 2 percent of AIDS cases can be traced to transfusions (Institute of Medicine, 1986), the blood supply is now considered to be generally free of HIV infection.

b. Testing protocols

The general practice in donated blood screening is to perform 2-3 EIAs and then a Western blot (WB) on repeatedly reactive samples. If the WB is negative, the blood is discarded and the donor's name is placed on a deferral list. If the WB is positive, the donor is notified by letter and asked to come in for counseling. In general, testing is confidential but not anonymous.

c. Epidemiological and cost data

Data on the prevalence of HIV among the blood donor population, and the costs of screening blood is relatively extensive. In the highly select population of blood donors, the prevalence of HIV infection is low--.02 percent for 12.6 million American Red Cross blood donations between April 1985 and May 1987 (MMWR, 1988).

A number of studies of the cost of screening blood donors have been performed. Eisenstaedt and Getzen estimated the average cost of EIA screening at $3 and $6 for WB confirmation. Processing costs for discarded blood were estimated to be $75/unit including a marginal recruitment cost of $6/donor. If HIV positive donors are notified and medically evaluated, the total costs per person are estimated to be $450 (Eisenstaedt and Getzen, 1988).

The cost of testing the 12 million units of blood collected in the U.S. in 1986 has been estimated at about $50 million (Bloom and Carliner, 1988). The cost per test is low because of volume contracts that organizations such as the American Red Cross have with labs. A 1986 estimate of costs incurred by the American Association of Blood Banks members per 100 donors was $100-$200 for reagents and equipment, $5-$10 for personnel, $12-$25 for retest and confirmation, $20-$32 for discarded red cells and components, and $10-$20 for recruitment and management.

L. Miike of the Office of Technology Assessment (OTA) estimated in his 1987 testimony before the House Committee on Business that it cost between $11,025-$19,082 to identify one truly positive blood donor specimen. Yet Eisenstaedt and Getzen's (1988) cost-benefit analysis suggests that the current testing procedures generate net economic benefits.

2. The Military

a. History of HIV testing

The Department of Defense initiated screening for HIV in 1985 for new recruits and for active-duty personnel in 1986 (Herbold, 1986). HIV testing is done as a routine part of the medical assessment of all applicants for military service and all active-duty personnel.

b. Testing protocols

The Army's procedures are an example of the extensive HIV testing procedures used by the Department of Defense. First, people with a high-risk background are discouraged from applying for military service. In the testing itself, repeatedly reactive EIAs are tested with the WB. Applicants who are positive on the WB are counseled and offered the opportunity of repeat WB testing with a second sample. If individuals have two positive WBs, they are ineligible for the service. Active-duty personnel who are positive are retained in the service but are restricted to U.S. duty. The Army has established a policy to retest active-duty personnel every two years (NY Times, 12/7/87).

c. Epidemiological and cost data

Data on the prevalence of HIV infection and the costs of testing in the military is relatively extensive, with more information available on applicants than active-duty personnel. Most of the data come from the Army since they have been on the forefront of testing of both applicants and active-duty personnel. Over 600,000 applicants to military service are screened per year at government expense (MMWR, 1988). From 1985-1987, the Army screened 1.4 million applicants and 800,000 personnel in training and on active duty (Barnes, 1987). As of December 1986, more than half of the 2.1 million men and women on active duty had been screened and the entire military service will eventually be screened (S.F. Chronicle, 3/25/87). The crude overall prevalence of HIV infection among the military applicants evaluated between October 1985 and September 1987 is 0.15 percent (MMWR, 1988). The prevalence among active duty personnel as of the end of 1986 was 1.3 to 2.1 cases per 1000 (S.F. Chronicle, 3/25/87).

Data is available on the costs of testing for the Defense Department as a whole and specifically for the Army. The Defense Department spent $79 million in fiscal 1986, $74 million in fiscal 1987, and plans to spend $52 million in fiscal 1988 for testing (Bloom and Carliner, 1988). The Army has a contract with Damon Labs to perform testing for $4.41 per specimen, including specimen transport, EIAs, WBs, and reporting (Burke and others, 1987). This contract was awarded after extensive proficiency testing.

3. Prisoners

a. History of HIV testing

Because of the high reservoir of infection and the potential for high-risk behavior among prison inmates, numerous states have implemented HIV testing programs for some fraction of the prison population. The extent of HIV testing varies widely by locality. In 1987, President Reagan ordered the Justice Department to perform HIV testing in all federal prisons, on all incoming and outgoing prisoners, and on resident prisoners every six months (Intergovernmental Health Policy Project, 1987). This policy has since been changed to random testing of new prisoners (Hammett, 1988). Most state prisons screen for HIV, but the majority use the test on a limited basis for diagnosis, in response to incidents, or for epidemiological studies. As of March 1988, six States were screening all inmates, all new inmates, or all inmates belonging to at least one high-risk group (MMWR, 1988).

b. Testing protocols

Testing procedures vary by locality. Prison systems vary as to whether they test all incoming inmates, all outgoing inmates, or all inmates on a regular basis. Although counseling is supposed to be provided, whether and how well this is actually done is difficult to determine. Testing is confidential, but confidentiality is difficult to maintain in the prison system, especially since many systems segregate persons who are HIV-positive and persons with AIDS from the rest of the population.

c. Epidemiological and cost data

Most studies have found that the HIV antibody prevalence of prisoners is higher than that of the general population, probably because prisoners overrepresent past or current IV-drug users (MMWR, 1987). A study by Truman and others (1988) on entering New York State inmates found a seroprevalence rate of 17.4 percent. Baker and colleagues (1988) studied 1,878 juveniles aged 16-17 in Los Angeles County Juvenile Halls and detected a seroprevalence rate of only 0.16 percent. Similarly, a study of 746 newly incarcerated inmates in Oregon found a seroprevalence rate of 0.8 percent. CDC is supporting additional seroprevalence studies. (S.F. Chronicle, 3/25/87)

Little data are available on the costs of testing. A National Institute of Justice study reported that an EIA costs $5-$6 if done in-house or at a blood bank, and $10 if done using a commercial test kit. The WB averages $75, with a range of $25-

$150 (Hammett, 1986). Although the current expenditures on testing are small (for example, Bloom and Carliner report that the Federal Bureau of Prisons spent $1 million in fiscal year 1986 and $3 million in fiscal year 1987 on testing and treatment), the costs could be much higher if mandatory testing was required for all prisoners.

4. Immigrants

a. History of HIV testing

The U.S. Public Health Service added HIV to its list of excludable infectious diseases on December 1, 1987 (McCance, 1988). The exclusion applies to immigrants from foreign countries, aliens living in the U.S. who apply for naturalization, and refugees.

b. Testing protocols

Procedures vary depending on the category of immigrants and their location. Physicians are appointed by the U.S. government to perform the medical exam that includes HIV testing. To be considered HIV-positive, the individual must test positive on repeated EIAs and a WB.

c. Epidemiological and cost data

Currently, there is currently very little data on prevalence or costs. The Immigration and Naturalization Service and the Department of State are beginning to collect data on the number of persons tested and the number of persons who test positive. The cost of the exam and testing is generally borne by the individual. The cost of the HIV testing to the individual varies widely, from no charge to over $100 (McCance, 1988).

5. Premarital

a. History of HIV testing

HIV screening can be compared historically to syphilis screening, which at one time was mandated by almost every state but which has now been repealed in most states.

In 1987, President Reagan called for the establishment of premarital screening programs (Gostin, 1987). Three States, Illinois, Louisiana, and Texas, have enacted statutes concerning premarital screening. In addition, Utah bans all marriages of persons with CDC-defined AIDS (Cleary, 1987). Texas legislated a "trigger point"--if or when the seroprevalence rate in the state reaches 0.83 percent, testing will be implemented (Gostin, 1987).

Bills to require premarital screening have been introduced in 35 states (Gostin, 1987). Other states have enacted legislation that requires education of couples regarding HIV before marriage.

b. Testing protocols

The states with premarital screening have various procedures. Both Louisiana and Illinois require written proof of having been tested for HIV. The results of the test are disclosed to the couple. Although the results and not recorded in medical records, they are reported to the state. Illinois has recently enacted a partner notification program whereby any partners in the previous year will be notified if a test is positive (Chapman, 1988). The actual test procedures and the criteria for a positive test vary by test site.

c. Epidemiological and cost data

Estimates of the prevalence of HIV infection in couples planning marriage are based on studies of blood donors. Cleary and associates, in their 1987 study of premarital screening, used a prevalence rate of 70 per 100,000 for men between the ages of 18 and 45 years, and 7 per 100,000 for all others. The number of people getting married is roughly 3.8 million per year (U.S. Department of Commerce, 1985). A study by Moody and others of marriage license applicants in Alabama found a seroprevalence rate of 0.21 percent using the EIA and WB method of detection.

Several reports have estimated the costs of premarital screening, both as currently implemented and if it was mandatory for all states. In Louisiana and Illinois, the cost of testing is borne by the individual. Testing charges have been reported ranging from approximately $20 to over $200 per person. The average cost in Illinois for one screening test is $29 according to a hospital survey (CDC, 3/7/88). Individuals cannot use the free, anonymous test sites since they must submit written proof to the state of having taken the test and anonymous test sites do not provide a certification of proof. Current data for Illinois indicates that the state is losing marriage license revenue because individuals decide to get married out of state to avoid the testing requirement. Testimony in support of repealing the Illinois law included the statement that it is costing $50,000 to detect a single AIDS case (CDC, 5/2/88).

Cleary and colleagues found that the range of charges for HIV tests is quite large. For their analyses, they assumed that the resource cost of an EIA series is $6, a WB would cost $50, and additional counseling costs for each person tested would be, on the average, $25. They estimated that the cost of universal premarital screening in one year would be greater than $100 million (Cleary and others 1987).

6. Prostitutes

a. History of HIV testing

Prostitutes are considered to be at high risk for HIV infection because they have numerous sex partners, engage in high-risk sexual behaviors, frequently use IV drugs, and often have a history of sexually transmitted diseases. Concerns about the spread of HIV infection by prostitutes have prompted three states, Nevada, Illinois, and Florida, to enact statutes mandating that prostitutes submit to HIV testing (Institute of Medicine, 1988). Nevada is the only state that has given counties the authority to legalize prostitution, so they are the only state that can require testing for HIV infection as a condition of employment. Other states have introduced bills to require screening when prostitutes are arrested or convicted.

b. Testing protocols

Testing protocols vary by location. In Nevada, prostitutes are tested before employment and then on a monthly basis.

c. Epidemiological and cost data

Seroprevalence among prostitutes is difficult to measure. Some studies report rates of 0 percent while other report more than 50 percent (MMWR, 1987). A study by Chiasson and associates (1988) of male and female prostitutes in New York City found that seropositivity in male prostitutes is related primarily to homosexuality and IV-drug use, while in female prostitutes, it is related to IV drug use and being the sex partner of an IV-drug user. There is also little data on the costs of testing.

7. Special Population Groups

a. History of HIV testing

There are several populations where HIV screening is either currently mandatory or may become mandatory, including Job Corps participants, clients of prenatal and family planning, drug treatment, TB clinics, clinics for sexually transmitted diseases (STDs), newborns, and wards of the State (the mentally ill or retarded, and foster children).

b. Testing protocols

Protocols vary but, in general, follow the CDC criteria for a positive test--a repeatedly reactive EIA and a positive confirmatory test.

c. Epidemiological and cost data

The only group in which mandatory screening is regularly being done is the Job Corps, where 60,000 applicants are being screened annually (MMWR, 1988). In the other populations, almost all testing is done on a voluntary, routine basis or when medical indications or high-risk behavior warrant it.

C. Issues Related to Mandatory Testing

1. Definition of Testing Costs

This is particularly critical for blood, tissue and organ donors since there are secondary costs involved, including the decrease in donations due to voluntary self-deferral based on the mistaken belief that HIV can be transmitted by giving blood, and the marginal cost of recruiting new donors.

2. The Impact of Changes in Test or Laboratory Performance on Costs

The level of test specificity is particularly critical to the blood banking industry. To ensure the safety of the blood supply, blood banks have tolerated high false positive rates and have discarded any initially reactive blood. L. Miike testified that the false positive rate for blood donors ranges from 11 percent to 69 percent depending on assumptions regarding test specificity and sensitivity, population prevalence, and lab performance. Concern about false negative rates for donated blood is also increasing. Ward and associates estimate that 1 out of every 40,000 to 50,000 HIV-infected blood donations escapes detection.

The false positive rate is also a concern of the military. The Army claims to have a false positive rate of 0.001 percent due to its proficiency system (Barnes, 1987). However, the false positive rate calculated by Miike ranged from 3 percent (male applicants) to 59.3 percent (female applicants).

3. Secondary Costs of Mandated Testing

The presence of mandatory testing policies for some population groups may affect the size and characteristics of the population groups. For example, some individuals may be discouraged from applying to the military or the Job Corps as a result of the mandatory testing policies. Some individuals may elect to be married out of state if their state of residence requires HIV testing for marriage license applicants. Furthermore, if mandatory testing were implemented at prenatal clinics, some women may forego needed medical care to avoid being tested (Lo, 1988). These secondary impacts should be considered when calculating the cost of mandatory testing.

D. Third-Party Initiated Testing

Third parties such as health insurers, life insurers, and health care providers may also initiate demand for HIV testing. Requiring an HIV test as a condition of insurance coverage or employment will affect total demand for testing and the costs of this testing. This section reviews the available information on demand for HIV testing by third parties other than the government. It specifically examines testing initiated by three different third parties: health insurers, life insurers, and health care providers. For each of these parties, the public policy with respect to testing, the test protocols used, and the available epidemiological and cost data on testing are discussed.

1. Insurers

Insurance is a means by which the economic losses experienced by a few members are redistributed to the entire membership. That is, each member pays an amount equal to the average cost per loss. Thus, the individual is spared from assuming the full loss. The probability that an individual within the group will be the victim of the loss maybe related to his/her characteristics; for example, smokers are more likely to develop lung cancer than nonsmokers. When the relationship between individual characteristics and expected loss is quantifiable, insurers may elect to separate individuals into different risk groups based on their characteristics. Insurance premiums within each group are set to cover the average cost of loss expected within the group. Groups whose members have lower than average expected losses will pay less in premiums than those whose members have greater than average expected losses. This type of risk-classification system is imposed to limit the amount of adverse selection experienced by the insurer.

Adverse selection occurs when individuals with a higher than average expected loss are pooled with individuals who have a lower than average expected loss. In order to cover the mean expected loss (assuming everyone pays the same premium), the premium paid by those with the low expected loss will exceed their actual expected loss; the premium paid by the individuals with the high expected loss will be less than their actual expected loss resulting in cross-subsidization. A certain amount of cross-subsidization maybe desirable. However, one result of excessive cross-subsidization is that low-risk individuals will opt out of the system or transfer to another insurer, to avoid high premiums. This result is termed "adverse selection". In the long run, premiums for the remaining individuals will need to be increased to cover costs. This will further motivate low cost individuals to leave the group. To minimize the extent of adverse selection, insurers use a risk classification system whereby individuals are sorted into groups based on their expected loss. Premiums for each member of the group are the same but they vary among groups.

Life and health insurers typically group applicants into one of three categories: standard, substandard, and uninsurable. Risks classified as standard have an expected loss that falls within some range of the standard. A typical standard for a life insurer would be life expectancy of a 30 year old male non-smoker. Individuals who fall within a certain range of this standard (say up to 125% or 150%) are classified as standard. Individuals in this group pay the same insurance premium for coverage.

Individuals with characteristics that place them outside the standard range are classified as either substandard or uninsurable. Cowell and Hoskins (1987) report that most life insurance underwriters will be willing to write policies for individuals expected to have losses that are 2 to 3 times the size of the expected losses of the standard individual. Individuals whose expected claims put them above 500 percent of the standard are generally classified as uninsurable and denied coverage. For those above 500 percent of the standard, it is felt that the probability of a claim becomes so high and the premiums so unattractive that few people will purchase the policy, and there will be a serious problem of adverse selection. However, even within this category insurers may issue policies if the risk group is large, for example persons with heart disease, and if the expected claims loss can be predicted.

The ability to classify individuals into these categories rests on the insurer's ability to quantify the relationship between the characteristics of an individual and his/her expected claims liability. It is within this context that insurers will demand HIV testing on the part of applicants. The HIV test is a tool that can be used as a risk classification mechanism. That is, a person's seropositive status can be linked to the insurer's expected claims payout.

2. Health Insurers

a. Current policies

HIV testing, as a condition of health insurance coverage, is an extremely controversial issue. To date, health insurers do not require testing for group policies. Currently, there are approximately 14.5 million non-Medicare individuals who hold individual policies (OTA, 1988). In addition, approximately 16 percent of Americans are uninsured. Some of these individuals may purchase individual policies in the future and be subjected to HIV testing. Also at risk of HIV testing are those individuals employed in companies that self-insure for health services.

Because of the Federal ERISA legislation, most self-insured plans can avoid State insurance requirements, including those that require benefit packages to include specific benefits. In addition, self insurers are not required to comply with anti-discrimination restrictions and are not required to participate in State insurance pools for high-risk individuals.

While not all individual policies are provided by for-profit insurers, (OTA reports that 9.3 million individual policies are issued by commercial insurers, 4.2 million by Blue Cross/Blue Shield, and 1 million by Health Maintenance Organizations), one would generally not expect a firm to issue a policy unless the present value of expected premium collections exceeded the present value of future outlays for medical care expenditures and administration that the insurer expects to pay on behalf of the individual applicant. As of spring 1987, 43 States had no regulations prohibiting health insurance companies from demanding HIV testing as a condition of eligibility for individual insurance policies (Faden and Kass, 1988). Direct prohibition of HIV antibody testing, however, does not imply that insurers cannot attempt to screen patients to identify those at high risk of acquiring AIDS. Questions on insurance applications that seek to identify a patient's sexual orientation, the requirement of an attending physician's statement, or the requirement of a T-helper cell count as a condition of insurance coverage are other means that insurers may use to screen out applicants with high expected expenditures. More subtle forms of screening include the refusal of insurers to market policies in specific geographic areas. As of 1987, 22 States and the District of Columbia forbade insurers from including questions on sexual preference on insurance applications. Because the majority of AIDS cases are concentrated in certain regions of the country, information on the number of states prohibiting HIV screening does not provide a very complete picture of the number of at-risk individuals likely to be affected by State policies with respect to HIV testing. Faden and Kass (1988) report that "Of the 10 jurisdictions that have reported the greatest number of AIDS cases to the Centers for Disease Control, six prohibit insurance companies from performing any screening at the individual level."

Requiring applicants to show proof of their seropositive status as a condition of insurability effectively drives up the cost of obtaining insurance to the individual and may result in the individual's decision to seek insurance coverage elsewhere. This occurs whether or not the insurer pays for the testing since the applicant will devote time to the testing process. Companies must balance the expected reduction in net premium revenue from the loss of profitable customers, against the gain from avoiding insuring those for whom the expected benefit payout exceeds premium revenues--those who may develop AIDS. Identifying individuals at high risk of developing AIDS is performed by insurers in three ways: 1) direct HIV testing or use of a surrogate test, 2) requiring an attending physician statement (APS), and 3) direct questioning of insurance applicants. The cost of screening to insurers will depend on the screening method used, the population screened (typically APS and HIV testing are targeted to specific populations that may be identified from the application itself--never-married males over age 30), and whether the insurer or the applicant pays for the screening. State policies can affect screening costs by limiting the use of certain screens, requiring screens be performed on an all or nothing basis, mandating that services such as counseling be provided in conjunction with screening, and defining acceptable screening protocols.

The benefits of screening will depend on the reductions in expected net payout achieved by refusing to insure a particular population group. These benefits will depend on the expected costs of treatment, which in turn are related to projected treatment regimen and price expectations. When treatment regimens change rapidly, and when disease progression cannot be accurately predicted, estimating the present value of future benefit payouts will be extremely difficult. State policies can also have a major impact on an insurance company's expected future benefit payments for AIDS patients. Expansion in public sector coverage as first payor for drug therapies, development of State risk pools, and provision of stop loss insurance by the state can all affect the expected financial liability faced by an insurer.

The decision on the part of a health insurer to demand HIV testing of applicants will be based on an assessment of the costs of testing relative to the benefits. State and Federal policies can affect either side of this equation, as can changes brought about by the private sector. Thus, in estimating insurers' demand for testing, it is important to model both the costs and benefits of such testing as viewed from the health insurer's perspective and as constrained by Government policy.

b. Testing protocols

Both the OTA of the U.S. Congress and the Health Insurance Association of America (HIAA) have conducted surveys of insurers regarding their use of HIV testing. The OTA reports that approximately one-half of commercial insurers routinely test individual health insurance applicants for HIV infection. Some companies test all applicants while others target testing to "high risk" applicants. Companies located in areas of high AIDS prevalence, such as New York and California, reportedly test all applicants. However, since HIV testing is prohibited in California, T-helper cell counts are used as a surrogate test (OTA, 1988). Companies use different definitions of high risk. A history of sexually transmitted disease is the most frequently cited description of high risk. Drug abusers and hemophiliacs are also often considered high risk as are transfusion recipients. However, some firms routinely test all males.

Eleven of the fifteen Blue Cross/Blue Shield firms questioned by OTA either screen or plan to screen individual applicants for AIDS exposure. However, only one of the plans directly tested applicants for HIV. The other plans rely on the application questionnaire or the attending physician's statement as a means of screening applicants.

Over one-half of all HMOs interviewed by OTA plan to screen individual applicants for exposure to AIDS. HIV testing is currently only performed by two plans and is being considered by a third.

Each of the insurance plans that performs HIV testing and that is located outside California uses the ELISA-WB method of testing. Firms in California that test use a T-helper cell count. Neither the OTA survey nor the HIAA survey collected data from health insurers on the counseling provided to applicants for whom they requested testing, or on the confidentiality safeguards they had in place for those applicants who test positive for HIV infection.

c. Epidemiological and cost data

Neither the HIAA survey nor the OTA survey requested data from insurers on the cost of HIV testing. Both surveys requested information on the amount of claims payments related to AIDS. However, the OTA study focused on current payout for AIDS as opposed to the expected value of total payments made on behalf of AIDS patients. The HIAA study similarly did not collect data on the present value of claims payouts. Also, the number of HIV tested persons denied coverage as a result of the test was not reported in either study.

The HIAA survey included 325 commercial insurers that provide health and life insurance. Each company was asked whether it considered applicants with AIDS, and with HIV seropositive blood to be a standard risk, substandard risk or uninsurable. One hundred percent of the respondents indicated that persons with AIDS are uninsurable, 91 percent considered seropositive individuals to be uninsurable, and 6 percent felt seropositive individuals were a substandard risk. Only 3 percent felt that a seropositive person was a standard risk.

The only data on the number of persons tested by insurers is that provided by the Home Office Reference Laboratory, Inc. (HORL), which is the principal lab used by life and health insurers. In 1986, HORL reported performing more than 128,000 tests for antibodies to the AIDS virus using EIA-WB and 25,000 T-cell tests (OTA, 1988).

3. Life insurers

a. Current policies

While group health insurance is generally available to workers through their employers, life insurance is more frequently purchased through individual policies. Consequently, the possibility of adverse selection with respect to life insurance is likely to exceed that for health insurance.

Many States subject life insurers and health insurers to the same regulations. California and Washington D.C. ban the use of the HIV antibody test by any insurer. Wisconsin permits testing but requires the individual's consent. In September 1987, Massachusetts adopted a strict regulation requiring each life insurer to draw up a policy of up to $100,000 worth of life insurance available to applicants who refuse to be tested for HIV antibodies. It also requires insurers to pay for both pretest and posttest counseling for applicants who take the HIV test.

The decision by life insurers to require HIV testing is made in the context of a cost benefit analysis. The costs of HIV testing are similar to those faced by health insurers and will be affected by state policy. The benefits are the reduction in claims paid by screening out individuals at high risk of death.

Using data from the San Francisco City Clinic (SFCC), Cowell and Hoskins (1987) modeled the transition from sero-positive status to death. The discounted present value of AIDS-related claims in a newly infected population using a 6 percent discount rate was estimated at $515 per $1000 of potential insurance.

The information presented above can be used to calculate the claims reduction from screening for HIV infection. Cowell and Hoskins (1987) provide an example. "If the HIV infection rate among all males age 20-59 applying for life insurance is 1 percent then testing all such applicants could be justified at a cost of less than $5 per $1,000. At a cost of less than $50 for a 3-test procedure of two ELISA tests followed by a WB test, an insurer might justify HIV screening for amounts of insurance as low as $10,000."

The value of HIV testing and consequently the demand for testing by life insurers will depend on the cost of the test, the size of the insurance policy being applied for, and the life expectancy of the applicant. Demand for testing by life insurers is positively related to the size of the policy being applied for and negatively related to the cost of the test. Thus, State or Federal policies that require testing of all versus some applicants, or that require insurers to provide counseling to all persons tested should reduce demand for testing by life insurers. Treatments that expand life expectancy of seropositive persons could also result in a change in classification from currently uninsurable by most insurers to substandard. This would give HIV-positive individuals the opportunity to purchase life insurance, albeit at a high premium.

The possibility of adverse selection in life insurance exceeds that for health insurance. Most health insurance policies are offered through employers to their employees as group policies. Individuals expecting to use relatively large amounts of medical care may self-select into the more generous plans. However, the potential for adverse selection rests primarily in the individual health insurance market that is relatively small. In contrast, of the $6.65 trillion in life insurance in force at the end of 1986, $3.65 trillion was written individually. In addition, the range in terms of policy size is extremely wide.

b. Testing protocols

Little information is available on the testing protocols used by life insurers. Since many commercial insurers offer both life and health insurance, one might expect the testing protocols used to be similar for the two groups. Results of the OTA survey of health insurers indicate that the overwhelming majority use EIA-EIA-WB as the testing protocol. As with health insurers, little information on the amount of pretest and posttest counseling provided to applicants is available.

c. Epidemiological and cost data

Data on the cost incurred by life insurers for HIV testing has not been collected in any systematic way nor has data on the number of applicants who have been tested for HIV infection. Cowell and Hoskins (1987) estimate that the rate of HIV infection among males 20-59 may be as high as 18 per 1,000. Based on existing data from CDC, they also estimate that approximately 30 percent of the estimated 750,000 drug abusers in the U.S. were infected with HIV by the end of 1987. In addition, 2.5 million are estimated to be homosexuals and another 2.5 million are estimated to have been bisexual during some part of their lives. Cowell and Hoskins estimate that approximately 30 percent of this population group was also infected with HIV by the end of 1987. The American Council of Life Insurers projects that $1 trillion of new life insurance policies were issued in 1987 and that about one-half of that new coverage was for males aged 20-59.

Using this data, Cowell and Hoskins estimate that with no testing 55,000 of the 7.5 million individual policies expected to be issued in 1987 would be for HIV-infected individuals for a total insurance amount of $4 billion. If the life insurance industry were to require HIV tests of all new male applicants aged 20-59, approximately 7.5 million tests would be performed. Estimates of the cost of such testing have not been made.

4. Health Care Providers

a. Current Policies

Demand for HIV testing initiated by health care providers consists of two types of demand. The first is motivated by a desire of providers to know the HIV status of patients both for patient management and to determine the providers' risk of exposure to HIV. The second is demand by hospitals and other institutions to have information on the HIV status of their employees for purposes including protection of patients from exposure to the virus, and requirements to file worker compensation and other disability claims.

The Institute of Medicine has encouraged the use of increased testing of patients as an "adjunct to patient care" (Institute of Medicine, 1988). Given the advent of AZT, which has been demonstrated to prolong life, HIV testing as part of a diagnostic workup for at-risk and symptomatic patients has been advocated by the IOM. Screening as an adjunct to infection control procedures in hospitals when invasive procedures are performed on suspected seropositive patients has also been advocated. However, large-scale hospital based screening programs of patients has not been supported by the IOM. Concern for patients' rights is of primary importance. In addition, the IOM is concerned that hospital implementation of screening programs could give health care workers a false sense of security.

There have been a limited number of studies of hospital use of HIV testing. Mottice and others (1987) surveyed 67 Veterans Administration (VA) hospitals to determine their approach to testing both patients and employees. They found that "patients are likely to be tested for diverse reasons, unlikely to be counseled about the test or be required to consent to it, and test results are given no special precautions." Of the respondents, 66 percent indicated that they did not use any extra precautions concerning patient confidentiality, and 80 percent reported using more stringent criteria for testing and result-reporting with employees than with patients.

VA hospitals based their decisions to test patients on a variety of factors. Ten of 62 respondents required the presence of risk factors and clinical symptoms prior to testing; 28

hospitals tested on the basis of symptoms only, and 24 hospitals screened high-risk patients at physician or patient request. Some hospitals required patient consent prior to testing, others did not. Counseling was required in only 38 percent of responding hospitals and was either not required, left to physician discretion, or performed only after a positive result on 11 percent of the cases. Sixty percent of the hospitals entered the results of the HIV test on the patient's chart. The study also found that 40 percent of the hospitals did not test employees for HIV infection even in the event of a blood or mucous membrane exposure. Those hospitals with the most AIDS cases maintained the strongest confidentiality provisions for patient and employee test results.

A study by Henry and associates (1988) of 189 infectious disease hospitals and 160 Minnesota hospitals found that in Minnesota, between 1985 and May 1986, 75 percent of all nondonor HIV antibody testing occurred in clinical settings, while only 25 percent occurred at the alternate test sites. This suggests that hospitals and clinics are an important part of the picture of HIV testing in the U.S.

Henry found that 34 percent of the infectious disease teaching hospitals and 57 percent of the Minnesota hospitals indicated that patient consent was rarely obtained when an HIV antibody test was ordered. In addition, 46.8 percent of infectious disease hospitals entered the test result directly into the patient record as did 67.3 percent of Minnesota hospitals. This suggests that many hospitals may not be concerned about confidentiality of information at least to the point of allocating resources to this end.

The Henry study did not provide information on the number of patients tested or on the cost of testing performed on patients by hospitals. The study also did not collect information on the type and amount of counseling provided. However, less than half of the infectious disease hospitals and less than 40 percent of the Minnesota hospitals reported having a specific educational program about AIDS and HIV antibody testing for house or staff physicians.

The above information indicates that there has been some federal encouragement to increase HIV testing in health care settings with patient consent. However, the providers themselves have not taken a consistent approach to implementing guidelines. Many hospitals test without asking for patient consent and provide little in the way of counseling or services to maintain confidentiality. Information on the amount and cost of testing currently undertaken in health facilities is extremely limited at this time.

b. Testing protocols

The information presented above indicates that testing protocols used by hospitals and other health facilities are extremely varied. The decision to test often rests with the physician. It is generally not known what battery of tests are used in the testing process. Many patients are unaware of the fact that they have been tested for HIV and many are not counseled about the test. The general absence of testing protocols among hospital providers may, however, reflect the fact that most have had little, if any experience treating AIDS patients. Those hospitals located in geographic areas with a relatively high incidence of AIDS may have well designed testing protocols with substantial patient counseling, as well as information systems designed to maximize security regarding the test results.

c. Epidemiological and cost data

The studies on health care providers use of HIV testing generally do not provide estimates of the cost incurred in performing the test or the number of tests performed. Since the decision to perform an HIV test often rests with physicians who may have different motivations for testing, it may be difficult to estimate total provider initiated demand. One could, however, make assumptions regarding the potential number of patients for whom an HIV test would be ordered. There were approximately 34.3 million hospital discharges in 1986. Hospitals employed approximately 4.4 million persons in 1986. If every person discharged from a hospital and all hospital employees were tested annually, up to 38.7 million testing episodes would be performed on these two groups.

Several studies on the seroprevalence rate of hospital patients have been performed. A study by Gordin and others (1988) of 606 patients admitted to VA hospitals found that 3.7 percent of the patients admitted tested positive to HIV antibodies. Nassar and associates (1988) provided HIV antibody testing to 2,694 persons at the University of California Davis Medical Center, where they found a 10 percent seroprevalence rate. The Davis Medical Center provides the majority of care to indigent persons in the community. Sherer and colleagues (1988) tested 576 individuals at risk of HIV infection at Cook County Hospital in Chicago. They detected a 36.6 percent seroprevalence rate among this high-risk population.

E. Issues Related to Third Party Testing

1. The Amount of Adverse Selection

Currently, the potential exists for adverse selection among applicants for individual policies, although the magnitude of adverse selection experienced by the insurance industry is unknown. The demand for HIV testing by insurers will be directly affected by how much adverse selection they expect to experience in a particular group.

2. The Role of State Policy in Affecting Insurer Demand

State policies can affect either the costs or benefits of HIV testing by insurers. The demand for HIV testing by insurers will consequently be directly affected by state policies.

3. Demand for Surrogate Tests

When states prohibit direct HIV testing, insurers have responded by using a variety of surrogate testing techniques. These surrogate tests are likely to differ dramatically from the HIV test in terms of specificity and sensitivity. A likely result is that many individuals whose test results are false positives will be denied insurance coverage in States that restrict HIV testing. Surrogate tests take a variety of forms ranging from T-4 cell counts to simple screening of applicants on the basis of marital status and place of residence. The ability to substitute these surrogate tests in areas where direct HIV testing is prohibited raises serious questions regarding the effectiveness of public policies that prohibit the use of HIV tests. The decision with respect to what tests should be included in the definition of HIV testing will affect the calculation of testing costs.

4. Joint Costs

When HIV antibody tests are ordered as part of a patient's diagnostic workup in a hospital, the HIV test may be only one of many tests performed on a blood sample. The problem of separating out the cost of performing the HIV test from the cost of the other diagnostic tests performed at the same time is a major problem in assessing costs.

5. Secondary Costs

Many hospitals have adopted infection control measures such as increased use of gloves to minimize the risk of transmission of HIV from patient to health care worker. It is questionable whether the increased costs of care associated with use of these protective measures should be attributed to lack of information about a patient's HIV status. Because of the lag time between becoming infected and testing positive to the presence of HIV antibodies, use of protective measures would likely continue even if all hospital patients were tested for HIV at the time of admission. In addition, the use of protective measures is likely to reduce transmission of diseases in addition to AIDS in the hospital setting.

6. Costs Related to Multiple Testing

Depending on the confidentiality of test results, patients whose seropositive status has been determined by one provider may undergo additional testing by another provider. The second testing, assuming it is spaced close to the first or performed on an already determined seropositive person, will yield no additional information.

7. Costs of Maintaining Confidentiality of Test Results

In determining hospital policy with respect to the security of patient HIV test results, the hospitals must weigh the cost of alternative security systems against the potential liability from divulging the information. Depending on the size of a hospital's caseload of HIV positive people and State law, liability exposure could be high or low.

8. HIV Testing Without Patient Knowledge

Many hospitals test patients without informing or counseling the patient. Consequently, obtaining information from individuals on third-party testing may lead to large underestimates of the amount of such testing that occurs. This may be more of a problem in some areas of the country than others.

F. Individually Initiated Testing

Demand for HIV testing refers to the number of individuals who wish to receive testing services at the existing price. Utilization is distinct from demand in that it refers to the number of persons who actually receive testing services. In instances where the number of persons desiring testing at the existing price is less than or equal to the available supply of services, then utilization and demand should be equal. However, if supply falls short of meeting demand then excess demand for services will develop and actual use of services will be less than demand.

Demand for HIV testing is somewhat different from the demand for an HIV test. Individuals who demand testing are seeking to determine their HIV status. In general, demand is for a testing "episode" rather than a particular HIV test. While there may be exceptions to this at private test sites, individuals going to most test sites will receive one or more tests to determine HIV status. The specific test protocol used is generally defined by the site and the same protocol is provided to all persons who seek testing services. Based on their risk group status and other behavioral characteristics, individuals may have some idea of their HIV status and the number of tests which will be performed on their blood to ascertain status. However, until they are tested, they will not know how many different tests have been performed. It is important to distinguish between the demand for tests and the demand for a testing episode. The analysis of demand we are proposing in this protocol focuses on the demand for a testing episode as opposed to a particular test. The distinction is important because it carries with it substantial cost implications. In a high-risk group, one can expect the number of HIV tests performed on an individual to be greater than when the individual being tested is from a low risk group. Consequently, the average cost per testing episode will be higher for individuals in high-risk groups compared to those in low-risk groups. The cost per case detected will consequently be lower when testing is applied to individuals in high-risk groups compared with individuals in low-risk groups.

The distinction between test and test episode also has implications for the definition of false positive and false negative rates. Test specificity and sensitivity, as defined in section I, refer to the outcome of a specific test. Test sites, in determining which labs to contract with for HIV test analysis, and labs, which in turn purchase the test kits from manufacturers, must weigh the false positive and false negative rates of each individual test against the cost in choosing which tests to use. False positive and false negative rates for a testing episode are somewhat different. A false positive in an episodic sense refers to someone who is determined to be HIV positive after the entire test protocol has been run (often two EIA tests and a confirmatory WVB) but is, in fact, negative. These individuals are likely to have been counseled as to their positive status and may have even entered a treatment regimen. False negatives are those individuals who have been determined to be HIV negative after the test episode but in fact are truly positive.

The false negative and false positive rates for a particular test episode will depend on the sensitivity and specificity of the individual tests used and their joint sensitivities and specificities, the quality of the personnel assessing the test result, and the test protocol itself (number of confirmatory tests used). Thus, in calculating the cost per true positive and false positive, it is important to distinguish between the rates per episode and those for a specific test.

1. Measuring Demand

Individual demand for HIV testing can be assessed in a number of different ways. From the individual perspective, one can examine the decision to obtain a test of HIV status over a certain period of time. A population based measure of demand might examine the percent of a population that elects to be tested during a certain time period. This decision can be viewed as being influenced by a number of factors, such as behavioral characteristics, income, health status, test confidentiality, treatment efficacy, and other economic and demographic characteristics.

For those individuals who elect to be tested for HIV status, two other measures of demand might be analyzed. The first is the selection of the particular site at which to receive the test. Some individuals may elect to receive their test at an alternative test site, while others may choose to receive testing at a private physician's office. The selection of the test site is likely to be influenced by the economic and demographic characteristics of the individual as well as such factors as perceptions regarding the confidentiality of the test process.

The second measure of demand for those that elect to be tested is the number of test episodes per person. Individuals may elect to be tested more than once during a time period. The decision to engage in multiple test episodes may be made for a variety of reasons. The presence of relatively high false negative rates shortly after infection with HIV may lead individuals who test negative at one point in time to repeat the testing process at a later date. Individuals who repeatedly engage in risky behavior as well as those "worried well" may also demand more than one testing episode per year.

Demand for HIV testing is somewhat different than demand for other goods and services given the general irreversibility of the test results. That is, with rare exception, individuals who seek an HIV test episode and receive a positive test result will generally not demand further testing since the results from any future HIV testing episodes will also be positive. Thus, the nature and determinants of demand are likely to change as the number of individuals who are HIV positive undertake testing to affirm their HIV status.

2. Determinants of Demand for HIV Testing

The economic theory of demand derives from the assumption that individuals maximize utility subject to a budget constraint. Goods and services convey utility and the individual is faced with the dilemma of allocating his/her limited resources to the purchase of goods and services in such a way that his/her utility is maximized. Individuals may derive utility from improvements in their own health status, the health status of others, engaging in risky behavior (unprotected intercourse, IV drug use), and a host of other goods and services.

Individual utility maximization requires that individuals allocate time and resources so that the incremental utility gained relative to the price of one commodity equals the incremental utility gained relative to the price of another commodity. Individuals must balance the utility gain from engaging in risky behavior against the loss in utility that comes about through a decrease in their own health status or the health status of someone else. In allocating income across goods and services, individuals may attempt to balance this gain/loss in utility through purchasing condoms, obtaining clean needles, or limiting engagement in risky behavior. Assuming individuals place a positive value on the health status of others as well as on their own, obtaining an HIV test can be viewed as an expenditure of resources (even if no out-of-pocket resources are expended, there are still time costs associated with obtaining an HIV test) that can yield a reduction in the probability that another person's health status will decline (an individual who tests positive and is counseled may respond by reducing his/her engagement in risky behavior). Additionally, if research indicates that health status (including life expectancy) for positive HIV persons can be increased through early treatment, there is an incentive to receive an HIV test in order to undertake measures (receive treatment) to improve one's own health status.

One of the difficulties in applying the concept of utility maximization is that it is difficult to analyze utility maximization over time. That is to say, individuals may engage in certain behaviors today, such as obtaining education that will yield benefits (higher incomes) in the future. Those individuals with short time horizons and high discount rates are less likely to engage in behavior today that will yield benefits later than are those individuals with low discount rates and longer time horizons. If, for example, IV-drug abusers have higher discount rates and shorter time horizons than gay men, they may be less likely to use protective measures when engaging in sex and may be less likely to seek an HIV test. Because utility is subjective (depending entirely on individual preferences), it is not possible to directly measure whether or not individuals maximize either current or lifetime utility.

There are, nevertheless, many factors that can be identified as affecting an individual's decision to be tested for HIV infection. Perhaps most important among these factors are the characteristics of the individual in terms of sexual behavior and drug use. Even assuming that no treatment was available to prolong life or improve the quality of life for HIV positive persons, some individuals would still demand to know their HIV status. Individual behavior in terms of future sexual practices and drug use may be altered through testing and related counseling. Individuals who test positive may wish to alter career plans, change financial behavior, or alter consumption decisions. Knowledge of positive HIV status implies reduced life expectancy as well as the possibility of reducing the life expectancy of others and may alter current and future behavior.

Thus, individuals who receive a negative test result may derive utility from having their negative status confirmed and may also alter behavior patterns.

The efficacy of treatments for both AIDS and HIV related conditions is likely to have a major impact on one's decision to be tested. Current evidence suggests that AZT may prolong the life expectancy of AIDS patients. As new and more effective treatments are discovered, demand for HIV testing can be expected to increase. In addition, if treatment efficacy is related to the time following infection when treatment is begun, there could be a major impact on demand for testing. The possibility of a vaccine also may exert a significant impact on demand for testing.

Factors that increase or decrease the transmissibility of HIV infection also are likely to affect demand. If there is no change in treatment efficacy, but a mechanism is developed that eliminates or greatly reduces the transmissibility of the virus, demand for HIV testing will likely increase.

Changes in test specificity and sensitivity also may affect demand for testing. Given the enormous emotional consequences of false positive test results and the frequency of occurrence of such results in low risk populations, individuals may forego testing. In addition, the current rate of false negatives among newly infected persons may cause some people to wait after a specific exposure incident before being tested or engaging in multiple testing episodes. If specificity and sensitivity are increased, the demand for multiple testing episodes may change, and the timing of testing episodes also may change.

It is important at this point to again distinguish between a testing episode and a test. Most individuals who currently elect to receive an HIV test are demanding an episode of testing. Once the decision to be tested has been made, individuals must then select the site where they wish to receive the test. While protocols may differ from site to site, virtually every public site performs the same protocol (usually an EIA with positives confirmed by a second EIA and a WB) on every individual. The exception to this is private clinics. Individuals who select a private clinic as the test site may elect to purchase a single test. For those whose initial test result is positive, demand occurs as a sequence of events. Individual demand for a particular test will be conditioned on the result of a previous test.

The degree of confidentiality surrounding the test will also exert an impact on demand for HIV testing. Anonymous testing provides the greatest level of security regarding test results. To the extent that there is discrimination against seropositive individuals (by insurers, employers or others), individuals will prefer anonymous testing. Confidential testing offers less security to the individual than anonymous testing. The degree of security provided depends on the extent to which access to test results is restricted.

The importance of the security of test results in affecting demand for testing will depend on the extent to which an individual's utility will be diminished as a result of the disclosures of test results. If employers discriminate against seropositive persons in their hiring practices, and if insurers, landlords, educational institutions, or society in general engages in discrimination against persons infected with HIV, then the security of test results may be critical in a person's decision to seek HIV testing. By contrast, if discrimination against seropositives is minimal, and there are legal avenues to pursue in cases of discrimination, the security of the test results will be less of a concern to an individual considering an HIV test.

Because public test sites generally do not charge individuals for performing an HIV test, one might assume that the price of the test is not a determining factor in demand. However, while individuals may not pay anything out of pocket, they nevertheless devote time to the testing process. Transportation time and costs, and waiting time are important components of cost faced by the individual. Therefore, the accessibility of the test sites, the queue at the site itself, and the wage rate, which reflects the foregone income per unit of time, of the individual will all impact on the demand for testing. Rugg and associates (1988) conducted a study to determine why some individuals, once tested, fail to return to learn their HIV test results. They found that higher return rates were associated with shorter delays experienced in waiting for the test once at the site, the comfort and nature of the setting, and smaller numbers of clients seen per week by the site.

Psychological and emotional characteristics of individuals are also likely to affect demand for HIV testing. Individuals who are extremely risk averse may demand more testing to "reassure" themselves that they are not at risk of contracting AIDS. Other individuals may simply prefer "not to know" their HIV status regardless of their risk group. The psychological elements associated with demand for testing may be affected by educational programs and counseling.

Finally, an individual's demand for testing can be influenced by income, age, sex, race, marital status, family size, and other socioeconomic and demographic characteristics. For example, even within a given risk group a 24 year old married woman contemplating pregnancy may have a different demand for testing than a 45 year old single woman planning no children.

As discussed above, an individual's demand to know his or her HIV status will be affected by a host of factors. Some of these factors, such as security regarding test results, discrimination against seropositive persons, and location and staffing of test sites, can be directly affected by public policy. Treatment efficacy, and test specificity and sensitivity will be indirectly affected by policy decisions affecting medical research and legislation that prescribes testing protocols and monitors lab performance. Some of the factors, such as an individual's socioeconomic and demographic characteristics, will not be influenced by policy decisions or can only be marginally influenced; for example, welfare programs will affect the level of income of different individuals.

a. Testing protocols

The testing procedures followed by test sites vary depending on the policies of local health departments, state regulations with respect to which labs are allowed to perform testing, and state policies with respect to confidentiality of test results. A small survey of selected local health departments provides some data on testing protocols used by publicly-funded test sites (United States Conference of Local Health Officers, 1987).

The survey collected data on the costs of HIV testing and the testing procedures followed. All sites provide pretest and posttest counseling, a complete testing episode (confirmatory tests when appropriate), and many include partner notification for persons testing positive. Counseling is performed by a variety of personnel, from "STD investigators" to physicians, and the time allocated for it varies widely. Pretest counseling sessions range from ten minutes in Columbus, Ohio to one hour in Waterbury, Connecticut. Posttest counseling takes longer for positive results than negative. Persons testing positive are counseled anywhere from 20 minutes to three hours, depending on the site, while persons testing negative receive on average 15 minutes of counseling.

b. Epidemiological and cost data

Despite the prevalence of HIV testing sites and the public investment in support of alternate test sites, little is known about the cost of performing tests on the population that seeks testing on an individual basis. As of May 1988, CDC requires test sites with which they have contracts to submit utilization data on HIV testing. Some local and state governments have also recently begun collecting cost data from their test sites. Until these data become available, however, the only source of information on costs and populations tested is individual surveys by researchers. Results of this research follow.

The local health department survey described above collected total cost data on positive and negative tests, the separate costs of the actual HIV test, and the cost of partner notification (for both venereal diseases and HIV infection). These data are presented in Table 5. Utilization and seropositivity rates are also included. The average costs of testing and counseling per individual range from $22 to $75, with a sharp distinction between the cost of a negative result, $12 to $26, and the cost of a positive result, $24 to $123. The cost of the HIV test alone ranges from $4 to $13 for an ELISA, to $25 to $85 for a WB. Other confirmatory tests cost $300 to $1,000 per individual. Only a few sites reported the cost of partner notification for HIV infected persons, which average $70-$80 per positive person in Portland, Oregon, and $273 per person in San Francisco (United States Conference of Local Health Officers, 1987).

The characteristics of the individuals who seek HIV testing of their own initiative tend to vary by site. From the few studies performed in this area, two trends are apparent: 1) the populations seeking testing have changed from the earlier stages of the epidemic to the present; and 2) public policies regarding the reporting of test results can have an impact on individuals' decisions to be tested.

Two studies have examined the changing patterns in the population tested at alternative test sites, one in California (Kegeles, 1988) and one in Upstate New York (Graban, 1988). In 1985-86 approximately 50 percent of the population tested in California sites was homosexual or bisexual males and 50 percent was heterosexual. Today there is a 3 to 1 ratio of heterosexuals to gay/bisexual men being tested at the sites. Most persons tested report exposure to HIV via sexual contact, although increasing numbers of healthworkers exposed via occupational contact are now demanding testing. The majority of those tested in California are thus not part of an identified high-risk group, but they have recently engaged in high-risk behavior (Kegeles, 1988).

A similar increase in the number of heterosexuals seeking testing over the past three years is occurring in Upstate New York (Grabau, 1988). A survey of all alternative test sites by researchers at the New York State Department of Health revealed an increase in the number of females and persons with no risk factors or only heterosexual contact seeking testing, and a corresponding decrease in nonwhites, persons with symptoms, IV-drug users, and homosexuals or bisexuals seeking testing. These changes reflect an increasing popular concern with heterosexual transmission of HIV, and result in a decreasing seropositivity rate at Upstate New York test sites.

Table 5. Costs of HIV antibody testing and counseling, contact tracing (VD, HIV) - Local Health Departments, March 1987

Health Department (tested per month)	Seropositivity	Counseling/testing costs	Test Costs	Contact tracing venereal disease	Contact tracing HIV/AIDS
Baltimore, MD 227	14%	$20 (negative): $75 (positive) (including test costs)	$5 (ELISA) $25 (Western Blot)	$15.40 —	— —
Chicago, IL 175	14.5%	$26-33 (average) (including test costs)	— —	— —	— —
Colorado Springs (El Paso County), CO 160	16%	$12 (negative): $200 (positive) (including test costs)	$4 (ELISA) $300-1000 (other)	—	$200
Colorado State	—	$17 (negative): $24 (positive) (excluding test costs)	—	$108	$108
Columbus, OH 400	18%	$22 (average) (including test)	$5 (ELISA) $35 (Western Blot)	—	—
Denver, CO 360	12%	$7 (pre-test) $21 (post-test, positive) $6 (post-test negative) (excluding test costs)	—	—	—
Gainesville (Alachua County), FL	9.3%	$48 (average) (including test costs)	—	$44 (average)	—
Portland (Mullnomah County, OR) 150 (average)	20%	$33.26 (average) (including test costs)	—	—	$70-80
Salisbury (Wicomico County), MD 17	10%	$16 (negative) $24 (positive) (excluding test costs)	—	—	—
San Francisco, CA 800	20%	$75 (average) (including test costs)	$13 (ELISA)	—	$273 (average)
Seattle, WA 250	22%	$22 (negative) $30 (positive) (including test costs)	—	—	—
Waterbury, CT 50	6%	$22 (negative) $123 (positive) (including test costs)	$6 (ELISA) $85 (Western Blot)	$30 (average)	—

Source: U.S. Conference of Local Health Officers

Some studies have found that individual demand is strongly influenced by the confidentiality and or anonymity of the results. For example, a trial program in Portland, Oregon offering anonymous testing saw a 125 percent increase in demand for testing by homosexual men, a 56 percent increase by female prostitutes, and smaller increases for other groups compared to utilization under non-anonymous conditions (Fehrs, 1988). By the same token, a new law in South Carolina requiring reporting of the name and address of all seropositive persons tested in the state caused a 51 percent decrease in homosexuals seeking tests (Johnson, 1988). A similar reporting law in Colorado that required reporting the names of all seropositive persons to the State health department but maintained confidentiality of the records produced no change in the population seeking tests in that state (Judson, 1988). Such studies imply significant public health effects of legislated reporting requirements.

A hypothetical survey of testing decisions explored these distinctions in more detail. Women seeking prenatal care at a private group practice setting in San Francisco were surveyed by Lo and associates (1988) regarding their testing choices under different reporting scenarios. Almost all women surveyed would agree to confidential HIV testing if it was medically recommended, but only half would do so if the positive results were reported to public health officials. One of ten women would forego prenatal care if testing was mandatory but confidential, and one in five would forego care if positive results were reported to the state. High-risk women were more likely to be deterred from care because of testing requirements than women at lower risk of acquiring HIV. These results suggest that public policies regarding test result reporting influence not only the individual demand for testing, but also the demand for medical services that sometimes accompany testing, (prenatal care in this case). Such effects must be considered in an analysis of the cost of legislative action regarding testing procedures.

The above discussion reviewed the available data on utilization and cost of HIV testing, seroprevalence rates in different population groups, and the factors that affect demand for voluntary HIV testing. In the following sections, a model of the average cost of HIV testing services provided by labs and test sites and follow this with a model of demand for HIV testing is developed.

III. MEASURING THE COST OF HIV TESTING SERVICES

A. Introduction

Cost of testing is defined as the value of resources used in the provision of an HIV test. These costs include direct testing costs, counseling costs provided in conjunction with the tests, costs of partner notification, and costs associated with maintaining confidentiality of client records. These costs will be incurred by various sectors of the society, such as by the individual being tested, the government, health care providers, and insurance companies. The resources used for HIV testing also may be used for other purposes (blood may be tested simultaneously for HIV and hepatitis; lab equipment may have multiple testing uses; prenatal counseling also may include HIV test counseling). Equipment resources may be used for more than one time period. These factors imply that the calculation of HIV testing costs is not a straightforward process, and much care must be taken in developing estimates of the cost of HIV testing.

This chapter presents the issues associated with estimating testing costs. The first issue concerns the problem of identifying what is included in the definition of cost. Following a discussion of these definition problems, a description of the different components of cost and what is included in each component is presented. Then, a description of the various ways of measuring testing costs is provided, and some of the existing studies on costs of mammography screening and screening for cervical cancer are reviewed. In conclusion, the determinants of the average cost of HIV testing and some of the special considerations associated with estimating costs are discussed.

B. Defining Costs

This section describes some of the difficulties and issues encountered in defining the term cost. Five specific issues are examined in this section: 1) the difference between expenditures, costs, and charges; 2) the problem of joint costs and joint products; 3) measuring time costs; 4) examining secondary testing costs; and 5) measuring the cost of early detection of HIV infection.

1. Expenditures Versus Economic Costs Versus Charges

It is customary to think of the terms costs and expenditures as interchangeable. Conceptually, expenditures are different from costs. Costs are related to a specific output, while expenditures are often calculated without relation to the output-time dimension. Furthermore, the economic cost of testing is different from an accounting cost. The economic costs of testing are defined as the opportunity costs or forgone value of resources used for a given type of test. To convert expenditures into costs, it is necessary to depreciate the capital equipment purchased in an accounting period. It also is necessary to estimate the value of the testee's time so that a full and accurate estimation of testing costs can be obtained. Most currently available cost figures are estimated from the agency budget or gross accounting ledger, which may underestimate or overestimate the costs of testing.

Charges refer to the amount charged by the lab to the testing site or by the testing site to the individual (or agency responsible for reimbursement). Depending on the profit motivation of the testing site, charges may be higher or lower than the average cost of testing. Also, charges may reflect the internal cross-subsidization of a testing agency. In estimating the economic cost of testing, one should calculate the value of resources used for the test, rather than use charge figures as an estimate of costs. Unless the lab performing the test charges the test site its average cost and the site in turn maintains cost data, it may not be possible to calculate the actual cost of providing a test.

However, even if test sites maintain cost data, it is not clear that costs incurred by the site reflect the efficient use of resources. The plethora of available evidence on cost based reimbursement points to the fact that paying costs does not guarantee efficiency. Costs are driven by reimbursement methods as well as input costs.

2. Joint Costs/Joint Products

The most common effect of joint costs/products is that a specific input may produce two or more distinct outputs. For example, the equipment used by labs to perform HIV testing also might be used for performing other clinical tests. When this occurs, one needs to develop some means of allocating equipment costs to its various functions.

A second example is the HIV testing process itself. HIV testing essentially serves two purposes. The first is to identify a person's sero-status. This information can then be used to identify appropriate treatment regimens for the infected person and help measure the extent of the AIDS epidemic. In accomplishing this purpose, HIV testing is a diagnostic tool. The second purpose of HIV testing is educational. One of the objectives of testing and counseling is to change people's risky behavior. Thus, the resources used in the testing process produce both an educational and a diagnostic output.

If one is to eventually make cost-benefit assessments regarding the use of HIV testing as a diagnostic tool, it is critical to accurately account for the costs of testing required for diagnostic purposes and to separate these costs from other costs such as those associated with education.

Several approaches have been used to deal with the problem of joint costs/products. One approach is an operations research method that calculates actual resources used in performing a test. For example, tracking individuals through the test process to determine the amount of counseling time, waiting time, and testing supplies required to establish an individual's sero-status and to counsel the person about his/her status.

A second approach to estimating costs is to prorate resource costs by output. Thus, if 40 percent of a piece of equipment's time in operation is devoted to HIV testing, 40 percent of the cost of the equipment would be allocated to HIV testing.

A final approach would be that of marginal costing. If a lab or piece of equipment is being used at less than capacity for one purpose and the additional burden on the equipment from performing a second function does not result in the purchase of additional equipment, the marginal cost of adding the second function is effectively zero. For example, if a hospital is already drawing blood from a patient to test for hepatitis, only the additional personnel and resources required to perform HIV testing should be included in the cost--the actual cost of drawing blood should be excluded. Similarly, if labs currently own or lease a spectrophotometer that is used at less than capacity, and HIV testing is added to the list of tests performed, there may be no additional costs associated with the provision of HIV testing.

3. Time Costs

Time costs are an important but often ignored component of HIV testing costs. This is particularly true if an individual faces an effective direct price of zero at a site. Under these circumstances time costs may comprise 100 percent of total testing costs from the viewpoint of the individual. Time costs primarily include waiting time and travel time. Consequently, factors such as the staffing patterns at the sites, hours of operation and geographic location of the site will directly impact on time costs faced by an individual.

The monetary value placed on waiting and travel time is generally calculated using a foregone earnings approach. That is, one attempts to assess the amount of earnings that an individual forgoes when he/she decides to be tested. For employed individuals, the value of time foregone is calculated by multiplying the individual's wage rate times the total amount of time devoted to the testing process. For unemployed persons and those not in the labor force, one needs to estimate the value of nonmarket production that is forgone.

4. Secondary Costs

Secondary costs are defined in this study as those costs that are directly impacted by HIV testing policies but are not considered part of direct testing costs. For example, in States that do not permit HIV testing without the patient's consent, or do not allow test results to be passed among hospital staff, that staff will often assume a patient is seropositive and use protective devices when providing care. The costs associated with this would be considered secondary costs.

In addition, if testing is performed anonymously or is not entered into the patient's record, then a certain amount of retesting of patients will occur. From the standpoint of ascertaining the patient's sero-status, some of the retesting will not be necessary. In estimating testing costs, it may be extremely difficult to separate out retesting costs. First, unless a patient has been determined to be a true positive, some amount of retesting is necessary to determine a patient's sero-status since it can change from negative to positive. Only when testing is very closely spaced can some amount of retesting be considered redundant. In addition, in many instances one will not be able to identify whether or not an individual has been retested. In light of the evidence presented later that indicates that many hospitals test patients without obtaining patient consent or informing the patient, it will be virtually impossible to identify cases of retesting.

5. Costs of Early Detection of Seropositivity

Early detection of seropositive status raises questions about both medical and social costs and benefits. Early detection may increase the cost of followup and treatment, especially if expensive treatments, such as AZT, are used by asymptomatic seropositive people. Early detection also imposes a psychological burden, since there is no cure for infection with the HIV virus and uncertain progression to AIDS. In this study, authors recognize that the costs associated with early detection of HIV infection as treatment costs rather than testing costs.

C. Components of Costs

In this section, the components of HIV testing costs are discussed and costs are broken down into five parts: 1) administration; 2) direct testing costs; 3) counseling costs; 4) partner notification and reporting costs; and, 5) cost of maintaining confidentiality.

1. Administration

Administrative costs are those costs incurred by the test sites, testing labs and manufacturers for such things as coordination of the testing process, maintaining records, and expenditures for outreach. These costs will vary by test site and location. For example, some States, such as California, permit the use of private labs for HIV testing, and the labs may incur marketing and advertising expenses that are built into the testing costs. Large test sites require management personnel to schedule counselors and coordinate outreach efforts. Administrative costs also are likely to vary by facility location and whether testing is done by contract or in-house.

2. Direct Testing Costs

Direct testing costs refer to the costs of actually performing the HIV test. Included in direct testing costs are the cost of the test kits, expenditures on personnel used to draw blood and assess test results, the value of equipment used up in the testing process, and other supplies directly associated with identifying an individual's HIV status. Direct testing costs will vary with the testing protocol developed at each test site. In addition, State requirements with respect to the training of lab personnel, performance standards placed on labs, and licensing requirements may affect direct testing costs.

3. Counseling Costs

The counseling costs included in this protocol include the pretest counseling provided at the test site and any posttest counseling session provided at the site. Counseling costs will be related to the training and education level of the counseling staff. In addition, the risk characteristics of the population being tested can also affect counseling costs. Counseling time per individual is likely to be higher than average when the individuals being counseled are drug abusers. Posttest counseling time is also likely to be greater for seropositive persons than for seronegative persons.

Some hospital test sites perform no pretest counseling on patients. Other sites may only provide posttest counseling to seropositive persons. In some instances pretest counseling may be performed in groups using videos. Other sites perform one-on-one counseling both pretest and posttest. The counseling protocols used in the different sites can have significant impact on this component of testing costs.

4. Partner Notification

One important component of testing costs is related to partner notification. These costs are likely to vary dramatically depending on the population group being tested, and the State laws in existence that govern partner notification and protect the liability of counselors and other health personnel who perform these activities.

The costs of partner notification will vary depending on whether partners are traced by voluntary or mandatory notification and the extent of the search. CDC estimated that it would cost clinics over $98 per positive sex partner identified, traced, counseled, and tested, and almost $91 per negative sex partner (Intergovernmental Health Policy Project, 1987). Another study that looked at the costs of partner notification found an approximate cost-per-contact test of $100 and cost-per-HIV-antibody-positive client of about $810 (Wykoff and associates, 1988). Costs will also vary depending on how much information is collected and reported to other agencies.

5. Costs of Maintaining Confidentiality

Test sites that perform anonymous testing may experience different costs of maintaining confidentiality of records than those that perform confidential testing. Similarly, alternate test sites that have had a great deal of experience in performing HIV testing and see a high volume of clients may incur different costs than other sites. Hospital sites may face particular problems, since they routinely perform large numbers of tests--the results of which are generally entered directly into the patients' records.

D. Measuring Costs

There are a number of different perspectives from which one can measure costs. The most useful perspective depends on the specific questions being asked. This section discusses four different ways to measure costs: 1) cost per test; 2) cost per test episode; 3) cost per true positive/false positive; and, 4) cost per true negative/false negative.

1. Cost Per Test

The cost per test is a useful measure because it can be used to calculate manufacturer or provider costs. From the perspective of the laboratory performing the test, the cost per test will affect decisions with respect to which test kits to purchase from manufacturers and which testing sequence to run. Labs will need to weigh test specificity and sensitivity against the cost of the test kits in making purchasing decisions. State standards with respect to proficiency testing and personnel training can also affect purchasing decisions made by labs.

In addition to the sensitivity and specificity of individual tests, the joint sensitivities and specificities of different tests will affect the amount of confirmatory testing done and the tests used to perform confirmatory tests. Labs may elect to use one, two, three, or even more tests depending on the cost and test characteristics of each test individually and in combination with other tests.

2. Cost Per Test Episode

The cost per test episode is most useful for measuring the costs of testing different populations. Per episode costs need to be distinguished from per person costs. A person can have more than one test episode over the course of some period of time. Each time the person seeks to have his/her HIV status determined is considered a test episode. Some test sites and labs are reimbursed on a per episode basis; thus, testing costs per episode will have a major impact on the finances of the test site or lab. California, for example, reimburses its ATSs on a per episode basis. Other States may elect other financing methods.

The per episode testing costs will vary depending on the risk characteristics of the population being tested. The number of different tests performed in any episode will be greater in high-risk populations as will counseling time and time spent notifying partners.

3. Cost Per True Positive/False Positive

The cost per true or false positive gives the most useful information on the true cost of identifying seropositive persons in different populations. Third-party testers, such as insurers, health providers, and State and Federal governments may be particularly interested in this measure of testing costs. One of the principal motivations for testing is to identify seropositive persons and move them into treatment programs and counsel them regarding avenues of disease transmission. If the costs of identifying seropositive persons are extremely high, governments may wish to devote resources to other activities such as broad based educational programs or programs designed to curtail IV-drug abuse.

Insurers must balance the costs of identifying seropositive persons against the expected liability they will incur if they insure those who test positive for HIV infection. The cost per true positive provides them with a measure of the true costs they face in screening applicants that can be compared with the reduction in benefit payments for screening out positive applicants. The cost per false positive provides an indication of the cost of eliminating those individuals who are in fact good actuarial risks from coverage.

Costs per true and false positive tests are particularly relevant to blood banks. Blood banks typically are willing to accept high false positive rates to insure the safety of the blood supply. Part of the cost of accepting a high false positive rate is that a great deal of safe blood may be discarded. Calculating the costs per true and false positive will provide information to donor agencies on the testing costs per unit of safe blood that is discarded.

4. Cost Per True Negative/False Negative

The cost per true negative provides a measure of the costs of identifying persons who are not yet infected with HIV and for whom counseling and other educational means may be used to prevent infection from occurring. When examined within the context of different risk groups, the cost per true negative also provides a perspective on the spread of HIV infection. In high incidence populations, cost per person tested will be relatively high, costs per true positive will be relatively low, and costs per true negative will be high (assuming a given specificity and sensitivity).

The presence of false negatives is particularly critical to the blood banking industry since a high false negative rate can seriously jeopardize the safety of the blood supply. The incidence of false negatives is inversely related to the incidence of false positives. Because of the consequences associated with being seropositive, ATSs are willing to accept higher false negative rates compared to blood banks. However, as the treatment available to seropositive persons improves and life expectancy increases, test sites may alter the acceptable balance between false positive and false negative rates.

E. Determinants of Average Cost

The supply of a service depends on the cost of providing the service relative to the price. As prices rise, supply will increase and new suppliers will enter the market. All else constant, an increase in the costs of performing HIV tests should lead to a reduction in the supply of services. The extent to which the price charged reflects the cost of production will depend on the elasticity of demand for testing services.

There are three major players in the supply side of the market for HIV testing services: manufacturers, laboratories, and test sites. In addition, the government also affects the supply side of the market through its role as a regulator (setting confidentiality requirements, requiring counseling, and specifying lab performance standards), and as a potential supplier (some States require that test evaluation be performed at State run labs). Together, these players will determine the average cost of performing an HIV test episode. Each of these entities can be regarded as providing a different type of output. The output of the manufacturer is the test kit. The output of the lab is the performance of an HIV test--the lab will have multiple outputs if it performs more than one HIV test. The output of the test site is a person tested and counseled. The test site output could be more finely divided into numerous outputs if one wanted to examine the number of samples of blood drawn, number of pretest counseling sessions, number of posttest counseling sessions, and number partners notified as separate outputs.

Section IV will assess different options for calculating output and different units of analysis that might serve as the basis of a cost analysis. However, whichever output measure is selected, one would expect average costs per unit of output to be related to the cost of inputs, volume of output, test protocol used and the population being tested. Each of these are discussed below.

1. Cost of Inputs

The higher the price of inputs, the higher the expected price of output. Inputs can be divided into two categories: labor inputs and nonlabor inputs.

Labor inputs at the lab refer to all personnel used to analyze a blood sample and report results back to the test site. The level of education and training required of the lab personnel will affect the cost as will the amount of time allocated to a specific test. For example, training requirements to perform WB testing may exceed those required to perform EIA tests. Consequently, labor costs will vary for these two tests.

At the test site a number of workers with special skills are required. Counselors are needed to perform pretest and posttest counseling. These counselors may be psychologists, psychiatrists, or social workers. Counseling may be performed in groups or one-on-one. Trained personnel are required to draw blood. Other personnel are required for record keeping. The amount and type of personnel employed at the test site will affect unit costs.

The second type of input is nonlabor input. Some nonlabor inputs are variable inputs--their amount varies with output. Test kits are an example of a variable input used by labs. Other inputs are fixed. Large equipment used in the testing process that depreciates over several years is an example of a fixed input. The laboratory building itself is also a fixed input. At the test site, video equipment used in conjunction with counseling would be an example of a nonlabor input as would the test site facility itself.

2. Volume of Testing

The volume of testing performed is likely to have a significant impact on average cost. If there are economies of scale, a doubling of output will result in a less than doubling of inputs. Unless input prices rise, the result is a decrease in average cost. Labs that perform many tests may have lower average costs than those that perform only a few tests. Also, when bidding on contracts with test sites, labs may bid less per unit on high volume contracts than on low volume contracts. The military has been able to contract with Damon Labs to perform HIV testing at a cost of $4.41 per person, well below the unit costs incurred by other test sites.

Test sites may also experience economies of scale. When only a few visits are provided, counselors and other personnel may be underemployed for part of the day resulting in high average costs. As visit volume increases slack time is reduced, and cost per unit of output falls. There may also be some labor saving cost-reducing technology that can be employed when visit volume is high and that may help in reducing average costs.

3. Test Protocol Used

The testing protocol used by the lab or the test site can have a significant impact on test costs. Proficiency requirements imposed on labs may influence the type of test used and the costs of the test inputs. For example, the military is a contractor which imposes strict proficiency requirements on bidders. This in turn can influence the quality of personnel and the specific test used.

Some labs may bid a price per test episode, including any confirmatory testing, or bid a price per test (per EIA or per WB). When bidding is done on a per episode basis and output is similarly defined, the test protocol may have an important impact on costs.

The protocol used by the test site may specify the amount and type of pretest and posttest counseling, and who will provide the counseling. ATS's generally perform both pretest and posttest counseling. Other facilities, such as hospital test sites, may offer little in the way of counseling. The services provided in the protocol will be an important determinant of the average cost of providing services.

4. Risk Group Being Tested

Finally, the characteristics of the risk groups being tested will have a major impact on average cost, particularly if costs are defined as costs per person tested. Labs that bid a fixed price per test episode will have higher costs in high incidence areas than low incidence areas because of the number of confirmatory tests that must be performed. Cost per test may not change and may even decrease due to the increased volume of testing. At the test site, counseling time per person is likely to be greater for those who are seropositive than those who test negative. It is possible that there is an interaction between the test protocol used and the risk characteristics of the population being tested. Some test protocols may be more cost effective among populations with high HIV incidence and others may be more applicable when applied to populations with a low seroprevalence rate.

F. Literature Review on Estimating Costs of Other Testing/Screening Programs

In this section, some of the studies that have assessed the cost of two other diagnostic tests, mammography and the Papanicolaou (Pap) smear, are reviewed. The similarities of these programs to HIV screening are discussed and the cost elements included in the studies are outlined.

Cost studies of screening tests for other conditions incorporate factors similar to those considered important in a cost study of HIV testing. A few such studies will be discussed here to illustrate approaches to cost issues in other medical contexts, specifically testing for breast cancer and cervical cancer.

Mammography is the most common technique used to screen women for breast cancer (aside from physical examination). It is a radiological examination of the breast for diagnosis of unidentified masses or for screening for potentially cancerous masses. HIV testing and mammography are similar in that a positive result must be confirmed with a subsequent test (in the case of mammography usually a needle aspiration of a lump, a biopsy, or an examination with ultrasound). The process of performing a mammogram usually includes an educational component, that is, patients are taught or encouraged to perform breast self exams as part of the procedure, which also parallels the safe sex counseling included in most HIV testing processes. One additional similarity is the conditions under which the tests are performed; both mammograms and HIV tests are often performed as procedures distinct from other medical exams, often at sites specific to that purpose alone.

On the other hand, two significant differences between the tests exist:

1. The demand for mammograms is usually initiated by a physician, through a referral for testing, while HIV testing is usually initiated by the individual (although in both cases there are important exceptions to this pattern).

2. The individual considering a mammogram has a strong incentive to have one performed because early detection of a malignancy significantly improves treatment outcomes. In contrast, there is still no proven treatment for HIV, so the individual's personal health will not directly benefit from early detection of the virus.

A review of selected cost studies of mammography reveals the methodological factors, such as components of costs and test effectiveness, that provide insights into such contributory factors in HIV testing costs (Bird 1987; Eddy and others, 1988; Moskowitz 1987; and Sickles and others, 1986). Cost components considered in these studies include fixed and variable costs of the initial test procedure, costs of followup testing, and time costs. Fixed costs include the mammography machine (usually amortized over five years), the film processing equipment, and additional items such as furniture for the office. Variable costs cover x-ray film and processing chemicals, other supplies such as linens and forms, and professional fees to technicians who perform the procedure and radiologists who interpret the films. Because a suspicious result from a mammogram always requires a followup diagnostic procedure, the expected costs of such procedures for all true and false positives are also included in the cost calculations. The final component of costs that is often acknowledged as a true cost, but for which quantification is rarely attempted, is the anxiety induced by the testing process.

The effectiveness of mammography in detecting cancerous lumps or masses is dependent upon the population screened, as is true with HIV testing, with the most important predictive factor being the age of the women tested. In HIV testing, risk characteristics such as IV-drug abuse and numbers of sexual partners are positively associated with HIV prevalence. HIV testing is more cost effective as a screening device in populations with these characteristics than in other population groups.

An innovative approach in mammography to lowering costs and increasing accessibility to the test is the use of a mobile mammography van. Such a van reduces time costs for women being tested because it is generally situated close to them (vans often go to worksites), and it reduces testing costs through operational procedures such as batch processing of films, a restriction to screening only (no diagnosis of existing lumps), and volume testing. In addition, the flexibility of location significantly increases the accessibility of the test to women who are limited by transportation or unaware of the availability of such a test.

Studies of cervical cancer screening employ similar concepts of costs. The Pap smear is a cytological examination of the cervix to identify precancerous abnormalities in the cells. As a screening technique, the Pap smear is an inexpensive, fast and simple test to identify cases that require further diagnosis. Like the HIV test, an abnormal result must be confirmed with a secondary procedure (usually a biopsy of the cervix). In contrast to HIV testing, the Pap is always part of a more general pelvic examination, and it is rarely performed alone. There is a strong incentive for early detection because highly effective treatment is available. The test is rarely used for diagnosis in conjunction with existing symptoms, it is only used for asymptomatic screening.

Studies of the cost of screening programs include the cost of the actual Pap test (but not the examination, because it would have been performed regardless of the Pap smear), which is measured through insurer reimbursement rates or the prices from labs that read the slides. Also included are time costs, and the expected cost of followup diagnosis of abnormal results--true and false positives (Schneider and Twiggs, 1972; Schweitzer, 1974).

Like other tests, the effectiveness of this test in identifying cases of cervical cancer is dependent upon the population being screened and its previous screening history. The false positive rate is generally less than 10 percent, and the false negative rate is approximately 10 percent (Schneider and Twiggs, 1972).

In conclusion, the cost components included in cost studies of screening programs similar to HIV are consistent across studies. Factors affecting test effectiveness are also similar--the prevalence of the condition in the population and the specificity and sensitivity of the test. The literature thus provides a precedent for the inclusion of such factors in a study of the cost of HIV testing.

G. Special Considerations in Estimating Testing Costs for HIV Infection

1. Lack of Centralized Information

HIV testing involves many different manufacturers, labs, and test sites. There is no centralized source of information on their differing costs of testing. However, more information, such as the CDC reporting requirements for publicly funded test sites, is being collected.

2. The Changing Nature of HIV Testing

HIV testing has been rapidly implemented, and is still in a state of flux. As more is learned about testing, the costs of testing will change. Factors such as new tests or new legislation on mandatory testing, confidentiality requirements, and partner notification could easily affect the costs of testing.

3. Difficulties in Obtaining True Information

Many of the issues surrounding the cost of testing are sensitive ones that will be difficult to assess. An example of this is the cost of maintaining confidentiality. Even with specific legislation on confidentiality, actual procedures may vary from the ideal. Workers will be reluctant to admit to not following these ideal procedures, so that the true costs will be difficult to obtain.

IV. ESTIMATING THE AVERAGE COST OF HIV TESTING

A. Introduction

The total cost of HIV testing is the product of the number of test episodes and the cost per episode. The number of episodes is, in turn, the product of the number of persons tested and the number of episodes per person. The cost per episode can be broken down into the two principal direct cost components: 1) direct testing costs per episode, and 2) counseling costs per episode. Administrative and reporting costs, costs of partner notification, and costs of maintaining record confidentiality are also components of testing costs. However, it is considerably more difficult to tie these costs to the individual being tested than the direct costs.

Direct testing costs per episode can also be broken down into cost per test (EIA, WB) and number of tests per episode. The cost per test will be dependent on the production function used by the laboratories performing the tests. The number of tests per episode will depend on the populations being tested, the sensitivity and specificity of the tests being used, and the testing protocol developed by the test site.

Counseling costs per episode can also be broken down into costs per session and number of sessions per test episode. Generally, people who are tested at an ATS will receive two counseling sessions per episode--one pretest and one posttest session. However, this is not true at many other sites. The cost per session will depend on the length of session, type of counselors used, and other counseling resources such as video equipment. The number of sessions per episode will depend on the test protocol used at the site and whether or not a client, who has been tested, returns to find out his/her test result.

In the next section, the options for estimating the average cost of HIV testing are described and an approach to estimating testing costs is recommended. Based on the recommended approach, existing data bases are surveyed and gaps in the existing data bases are identified. Then, a data collection strategy is proposed to obtain the necessary data to conduct the cost evaluation. Finally, an empirical model is proposed to analyze the data and develop estimates of the average cost of HIV testing. Seven separate measures of testing costs are outlined:

1. Average direct cost per test performed at the laboratory
2. Average testing cost per episode at the site

3. Average testing cost per test at the site

4. Average counseling cost per episode at the site

5. Average counseling cost per session at the site

6. Average total cost per true positive at the site

7. Average total cost per episode at the site

B. Options for Estimating the Average Cost of Testing Services

In this section, three options for estimating the average cost of testing services are presented. The first option uses the laboratory as the unit of analysis. The second relies on the test site as the unit of analysis, and the third option uses aggregate data from the States.

1. Laboratory as the Unit of Analysis

Virtually all test sites contract with labs to perform HIV testing. The major exception is hospitals that may perform HIV testing in-house. For those test sites that contract with labs, the amount paid by the site to the lab represents the direct cost of testing as viewed from the perspective of the test site. The amount received by the lab, however, may exceed actual production costs.

The economic cost of resources is the value of raw materials and technology that go into the production of a good or service. Laboratories may be viewed as combining the raw materials purchased from test kit manufacturers with the laboratory personnel, equipment, and the blood sample providing an output known as a test result. The cost of producing the test result will vary depending on the production techniques employed by the lab and the cost of inputs.

Assuming cost and output data can be collected from the laboratory performing the tests, the laboratory will be an excellent unit of analysis for estimating economies of scale and variations in average production costs resulting from differences in the type of tests performed, type of test kits used, and the amount and cost of personnel used to perform HIV testing. By using laboratory specific data, one will also be able to examine the relationship between characteristics of the labs (private versus State run) and the cost of the output.

There are two major drawbacks to using the lab as the unit of analysis in assessing average HIV testing costs. The first is that blood analysis is only a part of the testing process. Pretest and posttest counseling are major components of testing costs and are not provided by the lab. In addition, the blood samples themselves are drawn at the test site and transported to the lab. Consequently, a cost analysis based on the lab as the unit of observation would leave out major portions of HIV testing costs.

A second problem with using the lab as the unit of analysis is that the lab may not keep information by test episode or per positive and negative test. Such records may be kept in the short run while tests are being performed and then returned to the site once the analysis has been completed. Therefore, it is assumed that one will only be able to measure aggregate costs per HIV test performed.

In addition to concerns expressed above, the cost of collecting data from the labs also may be expensive. There is currently no national data base that includes information on lab testing costs and no data base that specifically addresses the cost of lab analysis of HIV tests. Consequently, such analyses would require survey design and data collection costs as well as costs for data analysis.

2. Test Site as the Unit of Analysis

The test site represents a second unit of analysis that could be used to assess the average cost of testing. With the exception of the actual analysis of blood, the test site generally performs all aspects of HIV testing including pretest and posttest counseling and partner notification (when included).

CDC is collecting HIV testing data from all States as a function of monitoring their funding programs. Funds are allocated to each State health department for HIV testing, and are then distributed by the states to individual testing sites according to cooperative agreements (contracts with testing sites). These sites are almost always publicly-operated, anonymous HIV test sites or STD clinics, but may include another type of public or private provider if they have contracted with the state to perform HIV testing. Data regarding all testing and counseling performed at these sites are collected by the State health departments and reported to CDC using the forms in Appendix 1. There are approximately 1,100 publicly funded sites.

Reporting on test volume and results by the test sites has been required by CDC as of May 1, 1988, and as of December 1988, about 75-80 percent of all project areas have reported their data. As of 1989, many family planning clinics will be offering HIV testing to all patients. Consequently, CDC expects the volume of HIV testing to increase in the future.

Because CDC does not require private physician offices and clinics that it does not fund to provide data on HIV test volume and results, the CDC data does not provide a complete picture of the amount of HIV testing performed at the different sites. However, beginning in 1989 the National Ambulatory Medical Care Survey will begin collecting data from private physicians and clinics on the number of HIV tests performed, the results of the test and the extent of counseling provided to the patient. The National Ambulatory Medical Care Survey (NAMCS) includes approximately 5,000 physicians. It uses a three stage survey design. The first stage involves probability samples of primary sampling units (PSUs). The second stage consists of a sample of practicing physicians within the PSUs and the third stage consists of the selection of patient visits within the practices of each of the sample physicians. The survey is used to generate national estimates of utilization of physician services by diagnosis and reason for visit. The questionnaire also collects information on the number and type of tests performed. The 1989 survey will be expanded to include HIV testing and counseling. This data can be used to supplement the data collected from the CDC funded sites to generate national estimates of the volume of HIV testing, results of the tests and amount of counseling provided.

While excellent data on use of testing are being collected, little data on cost of testing are collected from the test sites by CDC or The National Center for Health Statistics. CDC funds States for counseling and testing activities, allowing States to then determine how individual sites will be reimbursed. Individual States or local governments may require sites to file cost reports. There is no prescribed format for data collection; however, such procedures are not universal.

Because the test site generally provides all testing services with the exception of actual blood analysis, it can provide the basis for a comprehensive analysis of testing costs. A site-based analysis would enable one to examine the variation in testing costs resulting from the difference in counseling protocols controlling for such things as the risk characteristics of the persons tested at the site. One could also evaluate the impact of the number of persons tested on average cost per person controlling for risk group, type of test site, and characteristics of the test protocol. Assessment of economies of scale at the test site can have important implications for the size, location, and staffing patterns at publicly funded sites. In addition, whether the test site provides other services in conjunction with HIV testing may have an impact on costs. Information that would enable one to perform these types of analyses can only be collected from the test site.

The principal drawback to the use of the test site as the unit of analyses is that currently CDC does not require cost reporting by the sites. Thus, primary data collection, which could be expensive, would be involved. In addition, even if the data collection instruments were developed and a data collection strategy designed, hospital sites may pose a particular problem. Since HIV testing represents only a small part of their service bundle, it may not be possible to separate HIV testing costs from the cost of other services.

3. State as the Unit of Analysis

The final option in assessing testing costs is to perform aggregate analyses relying on a geographic area, such as a State or County, to serve as the unit of analysis. One could relate the average cost per person tested to the volume of tests performed, State regulations regarding lab performance and licensing requirements, the characteristics of the State population, and other aggregate characteristics related to cost.

The high concentration of HIV testing in a few States and the lack of Statewide testing data (except as collected by CDC) suggest that this avenue may not yield much in the way of policy relevant analysis. Even if testing costs and the number of persons tested were available at the State level, one would not be able to determine the impact of individual lab or test site characteristics on the cost of performing an HIV test or testing episode. The policy relevance of any Statewide analysis would be extremely limited even if accurate data were available.

C. Recommended Approach to Estimating Average Cost of Testing

A three level approach to estimating the average cost of HIV testing is recommended. Primary data should be collected from three sources:

1. A random sample of labs across the country
2. The number of HIV test sites including all those that have cooperative agreements with CDC, as well as the sites reporting in the NAMCS
3. A small sample of individual clients at a few test sites

The lab analysis will focus on the average cost per sample of blood analyzed. This analysis will examine only the costs associated with blood analysis and will not include the cost of drawing blood, which is performed at the site.

Analysis based on the test site will include total test cost per episode, testing cost per test, counseling costs per test episode, counseling costs per session, total costs per positive test result and the total cost per test episode. In addition we recommend using the test site as the basis for assessing the distribution of HIV testing costs by payer, and the costs of partner notification and maintaining confidentiality.

The sample of individual clients at the different sites will be used to calculate waiting and travel costs. A sample of individuals visiting the site for pretest counseling and blood drawing, and a sample of clients who have been posttest counseled will be questioned about their waiting and travel time at each step of the process. We recommend that this survey be performed at a number of representative test sites. However, it is not recommended that a large amount of resources be devoted to this part of the analysis. This study is to be exploratory in nature. If the study finds that there is wide variation in waiting and travel time costs among clients within a site, one may wish to expand the study design and increase the number of sample clients at each site. Alternatively, if client time costs are relatively constant within sites but vary greatly from site to site, one may wish to increase the number of sites in the analysis.

D. Data Requirements

1. Laboratory Data

The purpose of performing the laboratory analysis is to derive estimates of the average cost of performing an HIV test on a sample of blood. In calculating the determinants of average cost per test performed at the lab, the following types of questions have been addressed:

- What is the variation in average testing costs between state run labs, private for-profit labs and not-for-profit labs?
- Does the volume of HIV testing performed by a lab have an impact on average cost?
- How does the average cost of testing vary with changes in the proportion of the different tests performed? For example, as the percent of WB tests increases, do average costs per test rise?
- How do testing costs vary by region of the country?
- What impact do state policies with respect to lab regulations or licensing requirements have on testing costs?

To answer these questions one needs information on the number of different tests performed by type, over the course of some period of time such as a year. One also needs information on the costs associated with performing the HIV tests including supplies (test kits), personnel costs, and equipment costs. When personnel perform more than one task one will need information on the amount of time devoted to HIV testing. Similarly, if equipment is used to perform more than one type of test, one will need to prorate equipment expense by the amount of time it is used for HIV testing. For equipment lasting more than one year, it will be necessary to calculate the value of the equipment used up in performing the HIV testing. Laboratory administrative costs and general overhead will need to be allocated among the various services performed by the lab.

Data requirements are, to some extent, driven by the type of approach one wishes to use in estimating costs. The actual value of additional resources used to perform HIV testing is the marginal cost of testing. If one takes a marginal cost approach to estimating costs, the equipment costs and overhead costs, such as electricity and facility costs, would only be included in cost estimates if the addition of HIV testing to the firm's service package resulted in the addition of more equipment and space. If the new task could be accommodated with the existing fixed resources of the lab, then only the variable costs, such as test kits and personnel, would be included in a cost analysis.

In contrast, an average total cost approach to assessing production costs would prorate all fixed costs to HIV testing. While the marginal cost approach is technically superior as an estimate of resource costs, the average total cost approach may be more practical for estimation purposes. If it is possible to separately identify the fixed cost components of operating the lab or test site, it is recommended that a marginal cost approach to estimate costs be used. Even if such cost data are only available for a subset of labs or test sites, one may gain important insights by comparing the average and marginal costs derived from the data.

2. Test Site Data

The purpose of performing the test site analysis is to identify the variables that explain the variation in testing costs that exist between sites. The following list provides some of the questions that can be answered with the test site analysis:

- What impact do the risk characteristics of the client group served have on costs per test episode? Per test? Per true positive?

- What is the relationship between number of test episodes and direct testing costs per episode?

- How does the counseling protocol impact counseling costs per session? Per episode?

- What type of regional variations are there in costs per episode and per test?

To perform the site analysis, cost data will be needed that is broken down by category of function from the test site. Costs will need to be separated into counseling costs (if possible, pretest and posttest should be separated), costs of drawing blood samples and transporting them to the lab, cost of partner notification, and reporting and administrative costs. In addition, for those sites that perform other services besides HIV testing, such as prenatal clinics, costs for HIV testing must be separated from other costs.

Ideally, it would be best to have cost data from both the CDC funded sites and physician office sites. It may, however, not be possible for physicians to estimate the costs incurred for HIV testing. Therefore, it might be necessary to use CDC data for the cost analysis and charge data (or time input data) from physicians as a proxy for costs.

The same issues with respect to the marginal cost versus average cost analysis that applied to the lab also apply to the test site. Many test sites perform services such as prenatal counseling and rehabilitation or provide other health services in conjunction with testing. If HIV testing services are incorporated within the existing organization, then fixed costs should be ignored in calculating the marginal cost of HIV testing. Fixed costs must be prorated in some way to assess average total costs.

3. Client Data

The purpose of the client analysis is to estimate the time costs borne by the clients who receive HIV testing services. Some of the questions that will be addressed in this analysis are the following:

- How much time do clients spend traveling to the sites and waiting for services?
- Do test sites with longer than average client waiting times for the initial visit have a lower return rate (to pick up test results) than those with shorter than average client waiting times?
- What impact do the counseling and testing protocols have on client waiting time?

The cost of waiting and traveling consists of two components: 1) total time spent waiting and traveling, and 2) the wage rate. Wage rates reflect the opportunity cost of the client's time. Many of the clients receiving an HIV test may be unemployed or have wage rates close to zero. Others may have sick leave from employers so that they experience no wage loss. However, even for this population, time spent waiting and traveling does mean that individuals forego other uses of their time. The longer the wait, the greater the foregone opportunities and the higher the effective cost to the client.

Measures of waiting and travel time and wage loss occur at two points. Once when the individual comes in for pretest counseling and to have blood drawn, and second, when the individual returns for results. The decision to return for results may be conditioned by the prior experience of having blood drawn.

To estimate waiting and travel time costs, one needs information on both individuals who are receiving pretest counseling and those returning for results. This information should be collected from clients at a variety of different test sites so that time can be compared across sites. In addition to total time spent waiting and traveling, one needs information on the wage rate of the individual. Wages reflect the value of lost productivity while individuals travel to test sites and wait for testing to be performed.

E. Proposed Data Collection and Data Analysis

1. Laboratory Analysis

There has been little economic research to date on the market for clinic laboratory services and the determinants of lab costs or pricing structure. Perhaps the most comprehensive analysis was performed by Bailey (1979). Bailey calculated the determinants of nonhospital laboratory prices using data from 442 labs in California. While the study was performed prior to the advent of either the EIA or WB tests, Bailey did include an assessment of T-4 tests. He found wide variation in prices charged by the different labs for the same test. Bailey attempted to explain the price variation by looking at such factors as laboratory size, extent of service, level of automation, lab location, whether or not a pathologist directed the lab, and whether or not the lab was incorporated. He found little evidence that high test volume or a high level of automation were associated with low test prices. His findings did suggest that labs offering full services (those that took the specimen directly from the patient as well as analyzed it) charged higher prices for basic testing (lab analysis only) than labs that provided few services directly to the patient.

While the Bailey study provides considerable information on clinical lab pricing, it focuses primarily on assessing price differences rather than cost differences. In addition, the study was performed prior to existing HIV tests and was limited to labs in California. Nevertheless it provides a good methodological background and context within which one can assess lab costs.

There is little current data available on the determinants of HIV testing costs at the laboratory level. Some information is available by site on the prices paid for HIV lab testing. Prices charged for testing services may not be directly related to costs. To assess the determinants of lab testing costs we recommend collecting data from a stratified random sample of U.S. laboratories. The stratification criteria will be based on region and type of laboratory (blood or plasma collection center, hospital, commercial, or manufacturer laboratory). Cost information (see table 6) should be collected from accounting, reporting records, and the telephone interviews. In addition, lab characteristics such as ownership, location, and services offered should also be collected.

The required sample size to estimate the costs of HIV testing depends on the desired precision of the cost estimates, the variation (or variance) of testing costs, and the allowable sampling error. The desired precision of the cost estimates implies the range of confidence interval one would like to obtain, such as 95 percent or 90 percent. Thus, a T value is needed for the corresponding confidence interval--1.96 for a confidence level of 95 percent. The variation of the cost variable is expressed by the ratio of the standard deviation of the variable to its mean value, V. For a conservative estimate, it is assumed that the ratio is equal to 1. Finally, the allowable sampling error, P, for estimating the mean is needed to adjust the required sample size.

The required sample size for the laboratory survey can be calculated by the following formula:

$$N = \frac{T^2V^2}{P^2}$$

where **N** is the required sample size, **T** is the t value for the selected confidence interval of the variable, **V** is the ratio of the standard deviation of the variable to the mean, and **P** is the relative allowable sampling error. If we assume that **T**=1.96 (a 95% confidence level), **V**=1 (standard deviation is equal to its mean), and **P**= ± 10 percent, it implies that a sample of 384 laboratories is needed. On the other hand, if **P**=15 percent, a sample of only 94 laboratories is needed. Given that there are several thousand laboratories in the country and assuming a reasonable nonresponse rate (usually 60% percent for mail survey), 384 laboratories may be a reasonable sample size to start with. For a meaningful regression analysis, a sufficient number of sample observations is required to allow for reliable statistical inferences.

It is unreasonable to expect that laboratories are able to separate costs by type of test performed. Therefore, the data

Table 6. Data collection requirements for laboratory analysis

	Cost data requirements	
Cost category	Total costs	Percent of cost allocated to HIV testing
Total laboratory costs		
Operating costs		
Personnel		
- Physicians		
- Technicians		
- Others		
Supplies and materials		
- Test kits		
- Other		
Utilities		
- water		
- electricity		
- gas		
Maintenance and repair		
Other		
- rent		
- transportation		
- lab		
Overhead		
Equipment (annual amortization)		
Building		
Administration, tax		

	Utilization data requirements		
Type of HIV tests performed	Number of tests performed	Number of positive tests	Number of Confirmatory tests
EIA anti-body			
Western blot			
IFA			
RIP			
Antigen			
Gene amplification			
T-4			
Other			

different HIV tests performed, and the estimated proportion of costs allocated to performing the HIV tests. Some costs, such as the cost of test kits, may be tied directly to HIV testing. Other costs, such as personnel, may have to be apportioned based on the estimated amount of time that they spend performing the blood analysis. Some costs, such as facility costs, may be allocated to HIV testing based on the square footage of space used to perform the tests. The problem of cost allocation for HIV testing in the labs is somewhat similar to the problems that hospitals face in attempting to allocate costs for a specific service, for example delivery of newborns or cardiac surgery.

The dependent variable in the lab analysis will be the cost per test. The cost per test will be a function of a number of variables including the volume of tests, the percent of tests that are WB, the cost of inputs (personnel, supplies), and the characteristics of the tests used (specificity and sensitivity). Other factors such as whether the lab is a State-operated, private nonprofit or for-profit lab may also impact test costs. A brief formulation of the regression model is:

$$\frac{\text{Total HIV Testing Related Costs}}{\text{Total HIV Tests}} = f\,(\text{total HIV tests, percent of HIV tests that are of various types, wages of personnel, cost of test kits, rental fee per square foot in the area, size of lab, lab ownership, location of lab})$$

Ordinary least squares regression analysis can be used in the estimation. The regression coefficients on the continuous independent variables can be interpreted as the change in costs per test resulting from a one unit change in the independent variable. The coefficients on the dichotomous variables reflect the marginal impact on the dependent variable of having the characteristic represented by a 1 on the independent variable.

2. Test Site Analysis

The CDC has begun to require the approximately 1,100 publicly funded test sites to provide information on utilization of HIV testing services. However, cost information is not included in the data collected. To date, there have been no multivariate studies on the determinants of HIV testing costs using the site as the unit of analysis. CDC has made estimates of the amount of time it takes to perform pretest and posttest counseling to different population groups and has made estimates of some other components of testing costs. However, multivariate analysis has not been used to link specific aspects of the testing process, such as the testing and counseling protocols, to the cost of providing HIV testing. The relationship between volume of clients and client risk characteristics and average cost also has not been explored in any detailed way. If the CDC reporting requirements were expanded to include cost information areas by functional area, analysis of the determinants of cost could be performed.

In addition to cost data, additional process measures (the type of test used), the number of confirmatory tests performed, and number of initial false positive tests should be recorded. Also, information on the type of site, location of site, method used by the site to contract with labs and other services offered by the site should be collected along with the test and counseling protocols used by the sites. Finally, test sites that perform anonymous testing should be separately identified from those that perform confidential testing and those that do not have confidentiality provisions in place. When anonymous testing is performed, the test site may not maintain client records or perform any reporting of client HIV status to outside agencies. The cost of an anonymous testing episode may, therefore, be less expensive than the cost of a test episode that is not performed anonymously. Cost data is being kept by sites in various formats for reporting or management requirements. Table 7 provides an example of the cost data being collected by one county on each of the ATSs. If CDC implemented a policy to collect equivalent data from all test sites, and if this information could be supplemented with the information described above, it will be possible to perform a cost analysis using CDC data.

The dependent variables of interest in performing an analysis of costs by test site are presented below:

* Direct Testing Costs/Total Number of Test Episodes = Testing cost per episode

* Direct Testing Costs/Number of Tests = Testing cost per test

* Counseling Costs/Number of Counseling Episodes = Counseling cost per episode

* Counseling Costs/Number of Counseling Sessions = Counseling cost per session

* Total Site Cost/Number of Test Episodes = Total cost per episode

* Total Site Cost/ Number of Positives = Total costs per true positive test

Ordinary least squares regression analysis can be used to estimate the determinants of cost. An empirical formulation for each of the proposed regressions might be as follows:

Table 7. Example of cost data being collected by one locality

COST BY FUNCTION	TOTAL	Site One	Site Two
Administraton			
indirects			
Appointments			
indirects			
Blood Drawing			
indirects			
Laboratory			
indirects			
Pre-test Education			
indirects			
Post-test Counseling			
indirects			
Outreach			
indirects			
One-time			
Sequencer			
Computer prog.			
Surveys			
Videos/Materials			
Protocol			
One-time Total			
indirects			
TOTAL			
indirects			
GRAND TOTAL			
COST ANALYSIS			
TOTAL COSTS (including indirects)			
Number of tests			
COST PER TEST			
Breakdown			
blood drawing			
laboratory			
pre-test education			
post-test education			
TOTAL COSTS (including indirects but excluding one-time costs)			
Number of tests			
COST PER TEST			
TOTAL COSTS (excluding indirects and excluding one-time costs)			
Number of Tests			
COST PER TEST			
Breakdown			
blood drawing			
laboratory			
pre-test education			
post-test counseling			

Testing cost per episode = f (client risk characteristics, volume of test episodes, test protocol characteristics, wage rates of personnel, method of contracting with labs, type of site, site location)

Testing cost per test = f (test protocol characteristics, number of tests, wage rates of personnel, method of contracting with labs, type of site, site location)

Counseling cost per episode = f (client risk characteristics, counseling protocol characteristics, percent of clients who test positive, return rate of clients, type of site, wage rates of counselors, site location, number of episodes)

Counseling cost per session = f (percent of sessions that are posttest counseled, percent of clients that test positive, counseling protocol characteristics, type of site, wage rate of counselors, site location, number of sessions)

Total costs per episode = f (client risk characteristics, characteristics of test protocol, characteristics of counseling protocol, wage rates of personnel, type of site, site location, method of contracting with labs, number of tests per episode, number of counseling sessions per episode, number of episodes)

Total costs per true positive = f (client risk characteristics, characteristics of test protocol, characteristics of counseling protocol, type of site, site location, number of test episodes, cost per test episode)

The average cost function can be specified either in linear form or nonlinear form (log of number of EIA tests, log of number of Western Blots, or quadratic form). The relative statistical significance of these explanatory variables will provide information about the respective contribution of each variable to explaining the cost variation. Also, by using the estimated regression coefficient, one can predict the costs under different assumptions regarding the value of the independent variables. For example, the results of the analysis can be used to address the following types of questions:

- How much would average testing costs and/or counseling costs per episode change if there were a change in the underlying risk characteristics of the population?
- How would average lab testing costs change if all HIV testing were performed in state run labs?
- How would average testing costs change if the prices of the test kits fell or the nature of the test process were altered?
- How would average testing costs change if the process of confirmatory testing were to change?

Thus, the usefulness of this type of empirical formulation lies not only in its ability to quantify the determinants of cost but also in its ability to simulate costs under alternative assumptions. Given the changing nature of HIV testing and rapidly changing state policies with respect to testing, the ability to simulate testing costs under different scenarios is critical to the policy relevance of this protocol.

3. Client Analysis

The client analysis is to be a minor part of the cost estimation. It is performed to estimate the costs of client travel and waiting time. The recommendation is to identify a selected number of different test sites and to interview clients at each of the sites regarding travel time, waiting time, and their wage rate. It is recommended that approximately 6-10 different sites, such as prenatal, methadone, and ATS clinics, be included that represent different areas of the country. Approximately 10 clients arriving for pretest counseling and testing, and 10 clients arriving to receive testing results should be interviewed.

While the authors do not wish to place a great deal of emphasis on this aspect of the study, it is particularly important to include these costs in an analysis. First of all, test sites that provide a high volume of testing and are producing the volume with a minimal amount of staff will show up as having low costs per test episode in any cost analysis. This finding would not give an accurate assessment of costs if clients at these sites have higher than average waiting times for services. When this occurs, the site is simply shifting costs to the client. For example, cutting the staff at the post office will not reduce the cost of providing services if the length of the queue increases as a result of the staffing cut. If client waiting times are sufficiently long, some clients may be discouraged from obtaining services or may decline to return for results.

V. ESTIMATING THE DEMAND FOR HIV TESTING

A. Introduction

In this section, a model is developed for estimating the demand for voluntary HIV testing. . Because mandatory testing by the government and third-party initiated testing does not involve free choice by consumers (although consumers may elect not to purchase insurance from firms requiring testing, they are, nevertheless, constrained in their purchase decision), such testing should not be included in a model of individual demand. Third-party initiated demand can be estimated using the third party (health insurer) as the unit of analysis. However, evidence to date indicates that the magnitude of third-party testing is small with the possible exception of hospital testing. Government mandated testing also does not involve free choice by the individual. An evaluation framework that is suitable for government testing would be cost-benefit or cost-effectiveness rather than a supply-demand framework.

In estimating demand for HIV testing, consideration is given only to voluntary testing initiated by the individual. However, in estimating the national cost of HIV testing, the utilization estimates for third-party initiated testing will be combined with Government mandated testing and the author's projected voluntary utilization rates to develop national estimates of the number of persons who are expected to receive HIV testing, and the number of tests expected to be performed on the population.

In this section, options are presented for estimating a model of demand for voluntary HIV testing, and the strengths and limitations of these options are reviewed. Then, an approach is recommended to estimating demand, and the availability of data and gaps in existing data necessary to estimate demand are examined, and methods are suggested for filling the existing data gaps. Finally, an empirical estimation model is described.

B. Options for Estimating Demand for Testing

1. Individual as the Unit of Analysis

The first estimation approach uses the individual as the unit of analysis. Information is collected directly from individuals on their utilization of HIV testing services including the number of testing episodes and the particular site selected. Information on the risk group, economic and demographic characteristics of those individuals tested and those who elected not to be tested must be collected. Information can be collected either through in-person, telephone, or mail surveys. However, given the populations that are of particular interest, telephone interviews, and mail surveys may not yield sufficient information to conduct a demand analysis.

Information gathered on an individual basis will yield the most information on the characteristics that influence demand for testing and the magnitude of the relationship between a particular characteristic and the decision to be tested. The major drawback of collecting data directly from individuals is the cost. Primary data collection requires a substantial amount of resources. Questionnaire development, sample selection strategy, recruitment, and training of interviewers, field work, and data coding and entry are tasks that must be performed when primary data are collected. To justify the large expenditure of resources, a careful assessment is needed to determine the value of the information.

Collection of individual data that can be used to estimate demand for HIV testing poses special problems. Because of the low incidence of HIV testing among the general population, the study design may need to over sample individuals with high probabilities of being tested. Since a sizeable fraction of the population with high testing probabilities may be difficult to interview, the costs per interview will be high relative to the cost of performing the same interview on someone in the general population.

2. Test Sites as the Unit of Analysis

A second approach to estimating demand for HIV testing is to use the test site as the unit of analysis. Beginning in May 1988, the CDC began requiring test sites to provide information on utilization of HIV testing services. The data are collected on a quarterly basis from each of the alternate test sites. Information requested includes the age, sex, and ethnic distribution of the population tested, and on the population that tests positive. Data on the number tested and number positive by risk group (not broken down by age and sex) are also requested, as is information on the number of sex partners who were tested. Finally, the reporting form requests aggregate information by region on the number of sites of each type and the total number of client visits, number of clients pretest counseled, number tested, number found to test positive for the presence of HIV antibodies, and the number of individuals who received posttest counseling. Hospitals and private offices that do not have cooperative arrangements with CDC are excluded from the list.

If the CDC data are complete, they will provide a good indication of testing utilization. However, no data are collected by CDC on the number of persons who elect not to be tested. Unless the size and characteristics of this population are known, it will not be possible to estimate a demand equation for testing services and to identify the determinants of that demand using CDC data.

CDC currently performs its own estimates of testing utilization. They first estimate the number of visits to each of the various types of sites and apply to this number an estimate of the proportion of individuals who would be willing to receive an HIV test. Based on assumptions of the proportion of those tested who test positive, CDC then calculates the cost of testing and counseling provided to the different population groups. The CDC methodology focuses on those organizations that receive some level of Federal or State funding such as ATSs, drug treatment centers, family planning and prenatal clinics, and TB clinics. Private clinics, hospitals, and insurers are not included in their estimates. The CDC data and estimates can be used as a cross-check on our national utilization estimates derived from demand analysis.

3. State as the Unit of Analysis

The third unit of analysis that has been used to estimate demand for health services is the State. Numerous studies have combined Statewide data with Medicaid, Medicare, or aggregate utilization data to estimate demand for health services. There is a great deal of information available at the State level on economic and demographic characteristics and on State health policies. The Intergovernmental Health Policy Project at George Washington University has been collecting data on State policies with respect to HIV testing, making it possible to relate testing use to different State policies. The aggregate form of State data, however, makes it very difficult to isolate the impacts of different policies on individual testing decisions or the impact of individual characteristics on those decisions. In addition, because the incidence of HIV infection is concentrated in a few States, analysis based on 50 State data points could provide misleading results, since most States will have utilization rates close to zero. Finally, because demand is expected to vary by risk group, Statewide data on the number of persons in each risk group, as well as the number of users by risk group, is required to develop a complete picture of demand. States are not likely to have complete data on number of users or population by risk group.

The use of State data to analyze demand for testing has a major cost advantage over the use of individual data. However, the status of Statewide data collection, even in California, is such that reliable statistics on use by State and population by risk group are still not available.

C. Recommended Approach for Estimating the Demand for HIV Testing

To estimate individually initiated demand for testing, it is recommended that the individual as the unit of analysis be used. However, rather than design a completely new study, the authors suggest using the Health Interview Survey and the AIDS Knowledge and Attitudes survey as the basis for data collection. By adding some additional questions to the survey and possibly over sampling the high-risk populations, the data generated should be of sufficient quality to estimate individual demand for testing.

In the remainder of this section, a more detailed examination of the data requirements for the analysis, gaps in existing data, and a proposed data collection strategy are examined. Then, possible strategies are suggested for analyzing the data once it has been collected.

D. Data Requirements

Section II provided a detailed discussion of the factors that are expected to impact on individual demand for HIV testing. In order to estimate an individual demand equation, one needs to collect data from individuals on the various measures of demand and on all the factors that are expected to be associated with demand. Ideally, these data should be collected from a random sample of the U.S. population.

Three measures of demand for testing are proposed:

- whether or not the individual elects to be tested,
- number of testing episodes during the year, and
- selection of the testing site

The data base should include information on these three demand measures and on each of the individual characteristics that are expected to influence demand. In addition, information on State policies and laws affecting HIV testing should be included in the data base, since they also may have a role in affecting demand for testing.

The demand analysis will permit one to answer the following types of questions:

* What impact do individual risk characteristics have on the decision to be tested?

* How do individual perceptions regarding test confidentiality at the various sites impact the decision of which test site to use?

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- What impact do individual perceptions of treatment efficacy have on the decision to be tested?

- How do individual risk characteristics affect the number of test episodes per year?

- Do State antidiscrimination laws affect willingness to be tested?

Collection of individual data on the various measures of demand and the factors affecting demand is insufficient to guarantee the appropriateness of a data base for estimation purposes. The characteristics of the sample design and the size of the sample are also extremely important if one is to develop reasonable confidence intervals for the estimation model to be useful.

E. Proposed Data Collection

The principal survey available on HIV testing that relies on the individual as the unit of analysis is the AIDS Knowledge and Attitudes Survey (AIDS Survey) component of the National Health Interview Survey (NHIS). The NHIS survey is conducted annually by the U.S. Public Health Service. The NHIS is a continuous survey of a probability sample of the civilian noninstitutionalized population of approximately 50,000 persons per year. The sample is designed to represent approximately 1,000 households every week. Collected in the NHIS is a great deal of information on perceived health status, incidence of acute conditions, use of medical services, and detailed socio-economic and demographic data on each individual in the household. Interviewing is done in person. On August 10, 1987, a 15-minute AIDS survey was included as part of the NHIS. The AIDS survey is given to one randomly selected person 18 years and over in each household. Between August 1987 and December 1987, interviews with 5,597 persons (87% of the eligible respondents) had been completed. The same AIDS Survey was used from August 1987 through May 1, 1988. A revised questionnaire has been in place since May 2, 1988. The AIDS Survey is the only large scale survey of the population that asks specific questions on use of HIV testing services that is based on a random sample of the U.S. population. Approximately 800 persons per week are interviewed weekly using the NHIS and AIDS Survey, yielding over 40,000 observations per year.

There are two concerns with the potential use of the AIDS Survey as the data base for estimating the demand for testing. The first has to do with the actual content of the questionnaire and the usefulness of existing questions and responses in a demand model. The second is the sample design, particularly the ability of the NHIS to include IV-drug abusers, since they are an extremely important population group. Each of these issues will be addressed separately.

1. Expanding and Altering Existing Survey Questionnaire

The AIDS Survey and the NHIS as currently structured collect considerable information on the socioeconomic and demographic characteristics of the population interviewed. A copy of the AIDS Survey is provided in Appendix C.

Many of the knowledge questions on how one contracts AIDS and on an individual's experience with others who have had AIDS can be used as control variables in a demand analysis. Actual demand measures currently collected include whether or not the person was tested in the past twelve months, how many testing episodes they had, and where they received testing (hospitals are not included in the list of possible sites). The individuals tested also were asked whether they received the results of any of the tests, and whether they received counseling at the time they received the results. The questionnaire also asks individuals if they plan to be tested in the next 12 months and where they would go to receive a test.

The AIDS Survey questionnaire is somewhat vague in distinguishing HIV testing performed in regard to blood donation programs versus that performed for other reasons. Initial survey results indicated that while 7 percent of those surveyed reported having been tested for the AIDS virus, 12 percent indicated that they had donated blood since 1985. Results using the survey started May 2, 1988 are not yet available. However, the wording of the questions regarding testing continues to be vague. For demand estimation it is important to know how many test episodes individuals voluntarily initiated on their own and how many tests were the result of a blood donation, required by third parties (life insurers, health insurers) or required by State or Federal law (marriage license applicants, food handlers, prisoners). The survey does question individuals about whether they have been in the Job Corps, had a physical exam to join the military, or been in prison in the past 12 months. Both Job Corps applicants and applicants to the military are required to undergo HIV testing. The same is not true for prisoners, however, so that one cannot infer that a prisoner who was tested did so on a voluntary or mandatory basis. Even for Job Corps volunteers and military applicants, it is possible that these individuals, in anticipation of the mandatory testing requirements for the job, might elect to go to an ATS to determine their HIV status prior to application. The same might be true of marriage license applicants and other groups subjected to mandatory testing or affected by third party initiated demand (an insurance applicant might seek a test prior to application if he/she thinks that the company will require the test). The number of individuals who seek voluntary testing, and the test sites they select for receiving the test need to be carefully differentiated from testing that is required by law or by third parties if one is to derive estimates of individual demand.

For the AIDS Survey to be useful for demand estimation purposes, the questionnaire will need to separate the number of individually initiated voluntary testing episodes from those required by law or demanded by other third parties. Each test episode also should be associated with a test site. Because one of the most frequent reasons for HIV testing is blood screening, the survey should carefully separate out those whose HIV test was the result of a blood donation from those who voluntarily elected the HIV test. It is possible that individuals go to blood donation centers for the dual purposes of donating blood and being screened. If possible, these individuals should be identified.

Although many sites do not require any fee for HIV testing, others do. The NHIS does not systematically collect information on either health insurance coverage or out-of-pocket payments for health services. Both of these variables have been shown to be important determinants of demand and should be included in the questionnaire. In addition, the wage rate of the individual that is a proxy for time price should be included.

Some test sites perform anonymous testing, while others perform confidential testing. Confidentiality of test results has often been discussed as a potentially important factor that affects testing decisions both with respect to whether or not to test and where to go for the test. Since perceptions of confidentiality rather than reality is the demand determinant, individuals should be questioned about their perception of test result confidentiality, and their perceptions regarding the confidentiality provisions in place at the different sites, and whether this would (or did) impact on their selection of a test site.

The perceived efficacy of treating AIDS and HIV infection is likely to have a major impact on demand for testing. Individuals who view HIV infection as a precursor to AIDS and then death may derive little utility from becoming aware of their HIV status. Those who feel that treatment is available that can improve or prolong life may be more likely to be tested. It is, therefore, important to obtain information on individual perceptions of treatment efficacy. The same is true for test specificity and reliability. If individuals perceive test results to be unreliable and to generate many false positives, they may have a different demand for testing than if they felt the presence of HIV infection could be determined without error or with very small error.

The final set of variables that should be gathered are those on travel time. The existing survey does question individuals on their knowledge about where to go to get tested. For those who say they do know where to receive an HIV test, distance (in time) between their residence and the site should be collected. Ideally one would also like to measure waiting time. However, since the survey is asking for one year recall, it is very possible that such information cannot be obtained with any degree of accuracy.

With the addition or rewording of some of the questions in the AIDS Survey in the manner described above, the data generated could be used to estimate a model of individually initiated demand for HIV testing.

2. Altering Sample Design

The second major concern in using the AIDS Survey is the extent to which the sample represents the U.S. population, particularly IV-drug abusers. This problem is not unique to this study alone. In every health survey, the need to adequately survey those at high risk of low health status and susceptibility to disease is critical to obtaining unbiased estimates of disease prevalence. However, given the high incidence of HIV infection in specific populations, it is particularly critical to see that they are adequately represented. If NCHSR approves of the approach of using the AIDS Survey to estimate demand, the contractor, NCHSR, and NCHS will need to work closely together to assure the adequate representation of IV-drug abusers in the sample.

F. Data Analysis

1. Dependent Variables

As discussed earlier, three measures of demand will be used in the individual analysis: 1) whether or not the individual elected to be voluntarily tested; 2) the number of testing episodes during the past year; and 3) the test site for those who elected voluntary testing.

The first variable will take the value of 1 if the individual elected to receive a test during the past year, and 0 if the individual did not receive a voluntary test. Tobit or probit analysis will be used to relate the dependent variable to those factors expected to influence demand. Because of the high proportion of 0s in the sample, it may be difficult to obtain statistically significant coefficients on the demand variable.

One possible means of coping with this is to restrict the sample, say to men aged 25-45 years old who are not married. One could also estimate different regressions for different population groups.

The second demand variable is the number of test episodes per person. This analysis will be limited to the individuals reporting at least one voluntary test. Tobit analysis is recommended as the appropriate estimation technique.

The third demand variable is the selection of the test site. A possible categorization for test sites might be: ATS, and methadone, prenatal, STD, and TB clinics, and private physician office. The number of observations for this analysis will be the number of voluntary test episodes reported. Thus, a person reporting 3 test episodes during the previous year will show up as 3 separate observations. The model will assess the impact of factors such as risk characteristics and confidentiality perceptions on decisions to use one test site over another. Multinomial logit can be used as the estimation technique.

The variables shown in table 8 are expected to be related to demand for HIV testing. The first, risk group, can currently be ascertained from the AIDS survey. Variables 2 through 8 are currently included in the NHIS. Variables 9 through 17 are not included on either the NHIS or AIDS Survey and should be collected if possible. Because State policies can impact testing demand, one should include such policies as antidiscrimination legislation as a demand determinant. The Intergovernmental Health Policy Project at George Washington University is currently collecting information on State policies with respect to AIDS and HIV testing that could be incorporated in the analysis.

An empirical specification for each of the three analyses might look as follows:

Decision to be tested = f (risk characteristics, perceptions of test confidentiality , perceptions of test specificity and sensitivity, perceptions regarding treatment efficacy, socioeconomic and demographic characteristics, insurance coverage)

Number of testing episodes per person = f (risk characteristics, perceptions of test confidentiality, socioeconomic and demographic characteristics, insurance coverage, perceptions of test specificity and sensitivity)

Table 8. Variables associated with demand for HIV testing

1. Risk group (IV-drug uses, gay, hemophiliac)
2. Age
3. Sex
4. Race
5. Education
6. Marital status
7. Family income
8. Out-of-pocket cost
9. Health status
10. Insurance coverage
11. Distance to test site
12. Expected waiting time at the test site
13. Wage rate
14. Presence of symptoms
15. Perceptions regarding test specificity and sensitivity
16. Perceptions regarding confidentiality of test results (by test site if possible)
17. Perceptions regarding treatment efficacy for AIDS
18. Perceptions regarding treatment efficacy for HIV infection
19. State policies affecting HIV testing (confidentiality provisions, antidiscrimination laws, limits on third-party testing)
20. Other socioeconomic, demographic, and psychological characteristics that may be related to demand

Site selection = f (distance to site perceptions regarding test confidentiality at the site, risk characteristics, socioeconomic and demographic characteristics, insurance coverage)

Many of the independent variables in the model will be categorical variables. It is likely that there will be interaction effects between the variables that may affect utilization. For example, risk characteristics may interact with client socioeconomic characteristics in the determination of which test site a client selects. It is not possible a priori to specify all of the potential interactions between variables. Therefore, it is recommended that a set of preliminary analyses, such as cross-tabular analysis or analysis of variance, be conducted to indicate possible interactions that might be included in the regression model.

As with the cost analysis, the demand analysis will be used not only to estimate the determinants of demand but also to simulate demand for voluntary testing under different assumptions. Some of the questions that can be addressed with this model are the following:

- How would total demand for voluntary testing change if the at risk population perceived that test results were completely confidential?
- How would total demand for voluntary testing change if perceptions regarding treatment efficacy changed?
- How would total demand for voluntary testing change if the size of the IV drug using population increased?

In the section that follows (section VI), the cost model and the demand model are brought together to estimate the national cost of HIV testing.

VI. ESTIMATING THE NATIONAL COST OF HIV TESTING

A. Introduction

This section outlines an approach for estimating the national cost of HIV testing. It describes the data requirements necessary to make the estimations and reviews the available data and gaps in existing data. It then describes the assumptions necessary to make the estimation and the estimation technique. Finally, the section describes the process by which national estimates of HIV testing costs can be simulated under different assumptions regarding demand and average cost determinants.

B. Data Requirements and Estimation Procedure

The national cost of HIV testing is the product of the number of testing episodes and the cost per episode. In section IV, an approach was outlined to estimate the average cost per episode of HIV testing and the average cost per positive episode. The cost analysis presented in section IV also described methodology for estimating average direct testing costs at the site, average counseling costs at the site, and average cost per HIV test performed at the lab. Section V described an empirical model for estimating the voluntary demand for testing, selection of test site at which to receive testing, and the number of test episodes per person. The data requirements to estimate the national cost of HIV testing include the data necessary to conduct the cost and demand analysis as outlined in sections IV and V. In addition to the data required for those analyses, development of national cost estimates also will require data on the number of mandatory and third-party initiated tests since they are not included in individually initiated demand. Cost data on third-party initiated and mandatory tests will generally be included in the cost analysis since labs perform tests for all categories of demanders. However, if different agencies or third parties incur significantly different costs (as measured by agency or third-party expenditures to the labs, and cost differences in the provision of blood drawing and counseling services) the actual agency costs can be used to calculate testing costs associated with Government mandated and third-party initiated testing.

Table 9 shows the information required to estimate the national cost of HIV testing. For each of the population groups, information on the number of test episodes, the number of positive test episodes, the test site costs per episode (separated into direct testing and counseling costs), the number of tests by type, and the lab cost per test should be calculated.

Table 9. Data requirements for estimating the national cost of HIV testing

			Test Site Costs per Episode				
	Number of Test Episodes	Number of Positive Test Episodes	Direct Testing	Counseling	Total Site Costs per Episode	Number of Tests by Type EIA/WB	Lab Costs per Test
POPULATION GROUP							
Federal-mandated							
Blood donors							
Military							
Prisoners							
Immigrants							
Other							
State-mandated							
Prisoners							
Pre-martial							
Prostitutes							
Other							
Third party initiated							
Health insurers							
Life insurers							
Hospitals							
Employers							
Other							
Individually initiated							
Homosexual males							
IV drug abusers							
Females > 18							
Heterosexual males> 18							

Number of test episodes multiplied by the total cost per test episode reported by the site can be summed across each of the different demanders to develop an estimate of total testing costs.

To be useful for planning purposes, the methodology for estimating the national cost of HIV testing should be flexible enough to accommodate changes in such things as the type of tests available, changes in State policies with respect to testing, changes in the characteristics of the at-risk population and in AIDS treatment technology, and changes in the scope of mandated testing.

For each category on table 9, the process to be used to fill the cost and utilization data elements for the category and also the data requirements necessary to predict costs for the category under different assumptions of demand is described.

1. Mandated - Federal

To estimate costs of testing each of the federally-mandated groups, one needs to collect information directly from each Federal agency. The same data collection instruments that are used by CDC to gather information from the test sites (see Appendix B) should be used to collect data from the Federal and State agencies responsible for mandated testing. The testing and counseling protocols used by the agencies should also be collected, as well as information on the type of bid process used in contracting with labs, and site location. The information on utilization that is directly collected from the agency should be compared when possible to the testing use data collected in the NHIS and related AIDS Survey. For example, information collected directly from the blood banking industry should be crosschecked with national estimates of blood donor episodes derived in the NHIS. This comparison across data sources will be useful in highlighting discrepancies and identifying data problems. Because the NHIS is a survey of the civilian noninstitutionalized population, using this source to crosscheck information on the military and prisoners is not feasible.

Agency cost data for HIV testing should also be compared to the unit cost estimates calculated in the laboratory and test site analysis. This will provide insights as to whether the agencies are paying more or less for a testing episode than the estimated costs. A finding that there is significant cost variation could point to additional lines of inquiry as to the reasons for the cost differences (volume of tests contracted for, or lack of pretest counseling) that may form the basis for future research.

The utilization and unit cost estimates collected from the agencies can be directly used to calculate HIV testing costs for each of the federally-mandated groups. However, it is likely that federal policies with respect to mandatory testing may change over time. For example, currently only a fraction of Federal prisoners receive HIV testing. One possibility is that in the future all Federal prisoners will receive HIV tests upon entry into a correctional facility and at yearly intervals thereafter. The study should identify potential policy changes that can impact either utilization or costs per episode (a different test protocol may be implemented) and collect data that would permit analysis of the cost and utilization impacts of each of the potential policy changes. The ability to simulate the cost impact of different policies will greatly enhance the usefulness of the proposed study. For example, some of the population data that would be useful for simulation purposes include:

* Average yearly number of prisoners by age, sex, race, and risk group

* Number of newly convicted prisoners per year by age, sex, race, and risk group

* Number of discharged prisoners per year by age, sex, race, and risk group

* Number of military applicants by age, sex, race, and risk group

* Average yearly number of active duty military personnel by age, sex, race, and risk group

* Number of persons in other population groups for which HIV testing might be mandated (Peace Corps, State Department, CIA, FBI, employees in Federal hospitals and institutions) by age, sex, race, and risk group

The regression coefficients determined in the cost analysis could be used to simulate the average cost of a testing episode for a federally-mandated population group. For illustrative purposes, a very simple regression model has been outlined below that will demonstrate how the estimated model can be used to predict costs. Assume the regression model estimated is the following:

$$\text{Predicted Cost per testing episode} = B_0 + B_1\,\text{Episodes} + B_2\text{EIA, EIA, WB} + B_3\text{Pre} + B_4\text{Post} + B_5\text{Bid} + B_6\text{Positives}$$

Where:

Episodes = number of test episodes

EIA, EIA, WB = 1 if test protocol calls for EIA, EIA, WB
0 otherwise

Pre = 1 if pretest counseling is provided
= 0 otherwise

Post = 1 if posttest counseling is provided to seronegatives as well as seropositives
= 0 otherwise

Bid = 1 if lab contracts are awarded through competitive bidding
= 0 otherwise

Positives = percent of episodes that are positive

The cost per testing episode for a federally-mandated program could be simulated by applying the regression coefficients in the test site analysis to the data gathered from Federal sources on protocol characteristics, and volume of test episodes to calculate a predicted cost per episode. Actual costs per test episode could be compared to the predicted value to determine if federally-mandated programs are experiencing above or below average costs based on their program and client characteristics.

2. Mandated - State

The same strategy to be used in estimating federally-mandated utilization and costs should also be applied at the State level. This requires identifying the groups that each of the different States have targeted for mandatory testing and contacting each State agency responsible for testing a particular population to obtain utilization and cost data (some States may publish these figures).

Simulation modeling of both testing episodes and cost per episode can also be performed at the State level. For example, one could calculate total HIV test episodes under the assumption that all States were to require premarital testing. To perform such an analysis would require data from each State on the number of marriage license applicants and assumptions regarding the extent to which applicants might immigrate to other States to get married if premarital testing were required. One could also simulate costs per episode for this population using the results of the cost analysis. One would need to invoke assumptions regarding characteristics of the test protocol, the characteristics of the population to be tested, and assumptions regarding the value of other independent variables in the cost analysis. After identifying the assumptions regarding the independent variables, one could then calculate a predicted cost per test episode using the approach presented in the previous section.

In order to perform the total cost simulations for different State mandatory policies, one needs to multiply the predicted cost per episode by the number of episodes for each mandated group. To do this requires data on the size of each potential group. Population groups at risk of State-mandated testing and for which data on population size should be collected include the following:

- Average yearly number of State prisoners by age, sex, race, and risk group
- Number of newly convicted prisoners by age, sex, race, and risk group
- Number of discharged prisoners by age, sex, race, and risk group
- Number of marriage license applicants by age, sex, race, and risk group
- Number of individuals in population groups at risk for State-mandated testing (State hospital employees, patients in State institutions, foster children and other wards of the State, food handlers, employees in private hospitals and institutions, State police). This information is generally available and should be collected by the contractor in addition to the actual utilization and cost data.

3. Third-party initiated testing

There are several sources of data on the costs and utilization of third party-initiated testing. The most obvious source is the third parties themselves. In addition, most life and health insurers refer blood testing for HIV infection to Home Office Reference Laboratory (HORL), so that much of the utilization and cost data can be picked up from one source.

A second source of utilization data for third-party initiated demand is the NHIS and AIDS Survey that ask individuals whether the test was required and (if our suggestions on altering the questionnaire are accepted) who required the test. These two data sources can be used as crosschecks on each other.

The major problem in estimating utilization and costs for third-party initiated testing lies with the hospitals. Because many hospitals do not inform patients when they have been tested, the individual cannot be used as a source of data on hospital testing. In addition, because hospital labs perform a wide range of tests, identifying costs of HIV tests may be extremely difficult. One may need to separately survey hospitals regarding their use of HIV testing and impute an average cost to the number of episodes to develop cost estimates for this source of testing. A less costly and perhaps more useful approach would be to use the Hospital Discharge Survey to calculate the number of potentially high-risk patients and invoke assumptions regarding the proportion of these patients likely to be tested and the number of tests involved.

4. Individually-initiated testing

The total amount of testing initiated by individuals can be estimated by taking the weights applied to each person who reported initiating a test episode in the NHIS and AIDS Survey and inflating them to the United States population. The NCHS applies a weighting factor to each person in the sample that is roughly equal to the reciprocal of the probability of being selected into the sample. Additional adjustments also are made for nonresponse, post-stratification by age, sex, race, and ratio adjustments to the 1980 populations within race-residence classes. The result is a national estimate of individually-initiated testing episodes. The cost per episode calculated using the methodology in section IV can be applied to the number of testing episodes to calculate the cost of individually-initiated testing.

C. Assessing the Distribution of HIV Testing Costs by Payor

Calculating the distribution of HIV testing costs by payor is not straightforward. Individuals who receive HIV testing services will likely recall whether they paid out-of-pocket for the test or whether the test was covered by insurance. It is recommended that questions on out-of-pocket payments made by individuals and information on insurance coverage by included in the NHIS. This will provide information on the percent of voluntary testing costs that are covered by third-party insurance or paid out-of-pocket.

However, individuals who receive testing services at ATS's will often not know who paid for the service. Only if ATS's maintain revenue data by source of payor will we be able to calculate the distribution of testing costs by payor for voluntary testing. Assuming this to be the case one can develop estimates of the cost distribution of voluntarily-initiated service use by source (Federal, State and local, third-party insurance and out-of-pocket).

The cost distribution of mandated testing is more problematic. The Federal government can be assumed to bear the cost of testing Federal prisoners and military applicants (although this is, in turn, financed by taxpayers). State governments can also be assumed to bear the cost burden of specific population groups such as State prisoners. But who bears the burden of blood donor testing? Do the blood banks pass it on in the form of higher prices? Do insurance companies pass it on in the form of higher premiums? If Medicare or Medicaid eligibles receive a disproportionate amount of blood transfusions, do we assume that these programs finance a disproportionate cost of blood donor testing? These questions illustrate the complexities of estimating the distribution of HIV testing costs.

It is recommended that, if possible, test site revenue by source be collected and that the NHIS survey be used to calculate out-of-pocket costs for voluntary testing. However, the complexities involved in distributing the total HIV testing burden by payor are complex enough that a complete analysis of the cost distribution can be conducted as a separate analysis, outside the scope of the current protocol.

D. Simulating Demand and Cost Under Various Scenarios

Section V provided a methodology for estimating individually-initiated demand for a test episode and for the number of test episodes per person. The coefficients on the independent variables can be used to simulate the impact of a change in a particular demand factor on the probability that a particular individual (or the percent of a population of similar individuals) will elect to get tested. For example, perceptions regarding test confidentiality may be identified in the sample regression as an important determinant of demand. Individuals who perceive that confidentiality of test results is protected may be significantly more likely to be tested than those who do not feel that confidentiality is protected. The regression coefficients can be used to simulate the impact of a change in these perceptions on the probability of being tested. Similarly, utilization can be simulated under different assumptions regarding the number of persons in different risk groups, changes in perceived treatment efficacy, or a change in any other independent variable included in the demand regression.

Again, a extremely simplified model of demand is provided to illustrate the technique. Suppose the model takes the following form:

Decision to be tested = f (risk characteristics, perceptions regarding test confidentiality, race)

In this particular example, each of the independent variables is a categorical variable. There are 4 risk groups (IV-drug abusers, heterosexual males, females, and homosexual males), 4 race groups (Blacks, Hispanics, other non-White and Caucasian) and a single dummy variable set equal to 1 if the individual believes the test results will be confidential. Specifically, the variables are categorized as follows:

Y_i = 1 if the individual elects to be tested
= 0 otherwise

IVDA = 1 if the individual is an IV-drug abuser
= 0 otherwise

HETEROMALE = 1 if the individual is a heterosexual male (nondrug abuser)
= 0 otherwise

FEMALE = 1 if the individual is a female (nondrug abuser)
= 0 otherwise

CONFIDENTIAL = 1 if the individual perceives test results to be confidential
= 0 otherwise

HISPANIC = 1 if individual is Hispanic
= 0 otherwise

BLACK = 1 if individual is Black
= 0 otherwise

OTHER = 1 if individual is non-White but is not Black or Hispanic
= 0 otherwise

The omitted risk characteristic is homosexual males, and the omitted race is Caucasian. It is further assumed that the regression equation has been calculated as follows:

$$Y_i = B_0 + B_1\text{IVDA} + B_2\text{HETEROMALE} + B_3\text{FEMALE} + B_4\text{CONFIDENTIAL}$$
$$+ B_5\text{HISPANIC} + B_6\text{BLACK} + B_7\text{OTHER} + E_i$$

If the regression were calculated using ordinary least squares, the estimated coefficients would be interpreted as the marginal probability of being tested associated with a particular characteristic. Let us assume that $B_0 = .20$; this reflects the overall probability that a Caucasian homosexual male who believes test results will not be kept confidential will elect to be HIV tested. Assume further that $B_4 = .08$ and $B_5 = .02$. Now, the probability that a homosexual Hispanic male who believes test results are confidential will get tested can be calculated. This is done by combining the coefficients (.20 + .08 + .02 = .30). Thus, if there are 100,000 individuals with these characteristics, voluntary testing episodes for 30,000 would be expected. While this is an extremely simplified example, it illustrates how testing utilization can be simulated from the results of the demand analysis.

The regression results calculated in the example can be used to estimate the probability that individuals with a selected set of characteristics will elect to be tested. Table 10 illustrates the type of table that can be constructed using the results of the demand analysis. The probability calculated for each cell can be multiplied by the population in the cell to estimate the number of voluntary testing episodes.

Table 10. Predicted probability voluntarily initiating an HIV by selected characteristics

Confidentiality perception and risk group	Ethnic Group			
	Black	Hispanic	Caucasian	Other
Believes results are confidential				
IV-drug abuser				
Heterosexual male				
Female				
Gay male				
Believes results will be reported				
IV-drug abuser				
Heterosexual male				
Female				
Gay male				

Ordinary least squares analysis will generate biased predicted value when the dependent variable is categorical. Therefore, it is proposed that probit analysis be used in predicting the dependent variable. The coefficients of the probit model can not, therefore, be directly viewed as marginal probabilities. However, they can be easily transformed into marginal probabilities by using the standardized normal distribution table.

Given the regression results calculated in the demand equation, one can address the following questions:

- How will national demand for HIV testing change if the number of IV-drug abusers increases?
- What impact are changes in confidentiality provisions likely to have on voluntary HIV testing?
- What impact will a change in perceptions regarding treatment efficacy have on voluntary demand for testing?

Similar types of simulations can be made with respect to direct testing costs per episode and counseling costs per episode. The regression results obtained in the counseling and direct testing cost equations specified in section IV can be used to predict these different components of cost.

Simulation modeling can be used to address the following questions:

- How will costs per episode change with a change in the risk characteristics of the population?
- What impact will a shift to group pretest counseling have on costs per test episode?
- How will a change in the price of test kits or the confirmatory test process impact average cost per episode?

One can also combine the decision to be tested and selection of test site analyses with the average cost analyses to simulate national testing costs. The steps necessary to do this are as follows:

1. Using the decision to be tested, and episodes per person analysis, predict the number of test episodes for each population group.
2. Using the site selection analysis, predict the number of episodes occurring at each type of test site.
3. Using the cost analysis, data on the test and counseling protocols at the different sites, and the characteristics of the population at each site, predict an average cost per episode for each site.
4. Multiply the predicted average cost per episode at each site by the number of test episodes and sum across the test sites to develop national cost estimates.

There are a number of different approaches to simulating testing costs that can be taken. The key to developing useful simulations lies in the stability and precision of the underlying demand and cost analyses and the reasonableness of the assumptions. Prediction from regression coefficients can be very accurate when the underlying regression coefficients are stable, and when the policy being simulated is not a large deviation from current practice. However, when the coefficients have large standard errors and one is attempting to predict costs under a set of assumptions that represent a large departure from actual experience, the simulation results may not generate very good predictions of use of cost of HIV testing.

VII. RECOMMENDATIONS FOR IMPLEMENTING THE PROTOCOL

A. Proposed Implementation Strategy

The overall implementation strategy requires coordination with NCHS in the modification of the AIDS Knowledge and Attitudes Survey and the National Ambulatory Medical Survey and with CDC on the collection of cost data from the test sites. It also requires clearance from appropriate sources for the survey of a random sample of clinical labs currently performing HIV testing and for the survey of a sample of clients at various test sites.

The research protocol developed here can be divided into the seven research tasks described below:

Task 1 - Develop estimates of voluntary demand for HIV testing among the general population and the determinants of such demand

Task 2 - Develop estimates of the average laboratory cost of performing an HIV test and the factors that influence that cost

Task 3 - Develop estimates of the average cost of an HIV test episode performed at the test site. This task can be further divided into 6 subtasks

(a) identify the determinants of the average total cost per test episode

(b) identify the determinants of the average total cost per positive episode

(c) identify the determinants of the direct testing costs per HIV test performed

(d) identify the determinants of the direct testing costs per test episode

(e) identify the determinants of the counseling costs per counseling session

(f) identify the determinants of the counseling costs per test episode

Task 4 - Develop estimates of the cost of client waiting and travel time at the test site

Task 5 - Develop estimates of the utilization and costs of mandatory and third party initiated testing

Task 6 - Develop estimates of the national cost of HIV testing

Task 7 - Provide simulations of HIV testing use and costs under different scenarios

Tasks 1 through 5 can be carried out independently and may be conducted concurrently. Tasks 6 and 7 are predicated on the successful completion of the first 5 tasks (with the possible exception of task 4).

The data needed to accomplish the first task will come directly from the National Health Interview Survey supplemented by the AIDS Knowledge and Attitude Survey. It may be advisable for NCHSR and NCHS to coordinate a task force composed of economists, AIDS researchers, survey design specialists, and epidemiologists to assess the existing questionnaire and suggest modifications to the questionnaire and the sampling design in order to obtain the necessary data elements to permit the estimation of demand. Of particular concern is the development of a sampling strategy that would take account of the need to obtain information from IV-drug abusers.

The data needed to accomplish the second task will come from a sample of labs across the country. As a prelude to this task, it will be important to collect information on the number of labs by ownership, size, and service mix in order to develop an appropriate sampling frame. One may wish to pretest the cost questionnaire to determine the extent to which labs are able to separate fixed and variable costs.

The data needed to accomplish task 3 are from two sources: 1) data collected by CDC from the alternate test sites, and 2) data collected from NCHS in the NAMC Survey. As with task 1, it may be helpful to develop a task force composed of representatives from NCHS, NCHSR, and CDC to coordinate questionnaire development. This same task force can be used to oversee the data collection activities for task 4.

Task 5 requires the collection of data from insurance companies, the Federal Government and other third parties. To successfully accomplish this task, it might be helpful for NCHSR to contact representatives from the Health Insurance Association of America, Group Health Association, Blue Cross/Blue Shield, the Red Cross, and major Federal agencies involved in testing to solicit their cooperation and support.

The accomplishment of tasks 6 through 7 should not require additional data collection. However, since the successful completion of these tasks is predicated on the success of prior data collection activities, one may wish to appoint a small oversight committee composed of a member from each agency involved in data collection and NCHSR to guide the project during the final tasks.

B. Specific Activities

The activities to be performed under this protocol include project monitoring, study design, data collection and processing, data analysis, and report writing. A 30 month time frame is suggested for the research. The activities to be performed at each stage are outlined in table 11 and described below:

1. Project Monitoring

Very important to the successful implementation of these studies is strong coordination of each of the proposed tasks. Because the development of national cost estimates and the ability to perform simulation modeling is conditional on the success of all other tasks, it is critical that all aspects of the protocol are well managed. Also of substantial importance is the coordination with CDC and NCHS to collect the necessary data for the demand and test site analysis.

2. Study design

Study design activities are those related to the development of the research plan for carrying out each of the seven tasks. The basic activities involved in each task are as follows:

Task 1 - Develop estimates of voluntary demand for HIV testing

- coordinate with NCHS to develop questionnaire
- develop conceptual and empirical model for demand estimation
- specify empirical techniques to be used in the analyses

Task 2 - Develop estimates of the average cost of HIV testing by labs

- identify tests to be included in the definition of HIV testing
- establish definition of cost
- develop questionnaire
- design sampling framework
- develop conceptual and empirical estimation model
- specify empirical techniques to be used in the analysis

Task 3 - Develop estimates of the average cost of an HIV test episode

* coordinate development of cost questionnaire with CDC
* coordinate with NCHS on the NAMCS questionnaire
* assess the need for supplemental data collection (hospital labs, private) and develop strategy for obtaining data
* develop conceptual and empirical model
* specify estimation techniques

Task 4 - Develop estimates of the cost of client waiting and travel time

* develop questionnaire
* identify sites at which clients will be interviewed
* specify the method of selecting clients for interview
* develop conceptual and empirical model
* specify estimation technique

Task 5 - Develop estimates of utilization and costs of mandatory and third-party initiated testing

* identify data elements to be collected

    - utilization
    - cost
    - protocol descriptions
    - regulations and laws governing testing

* specify estimation techniques

Task 6 - Develop estimates of the national cost of HIV testing

* identify assumptions which are necessary to develop the estimates
* specify methodology for estimating the different components of cost

    - number of episodes
    - cost per episode

* specify estimation techniques

Table 11. Proposed time frame for implementing the protocol

Research Tasks/Quarter	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
1. Project monitoring	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2. Study Design																
Project 1	X	X	X	X			X	X	X							
Project 2	X	X	X				X	X								
Project 3	X	X	X	X				X								
Project 4		X	X				X									
Project 5		X	X				X									
Project 6				X	X	X					X	X				
Project 7				X	X	X					X	X				
3. Data collection and processing																
A. Data collection																
AIDS Survey					X	X	X	X								
Lab Survey					X	X	X	X								
Test Site Data					X	X	X	X								
Client Survey					X	X										
Government, Third Party			X	X												
B. Data Processing																
Data Coding							X	X	X							
Data Entry							X	X	X	X						
Data Cleaning											X	X				
Develop analysis files											X	X				
4. Data Analysis																
Descriptive											X	X				
Demand													X	X		
Lab Cost													X	X		
Test Site Cost													X	X		
Client Cost												X	X			
5. Report Writing																
Reports on Project Funding											X	X	X	X		
Final Report															X	X

Task 7 - Provide simulations of HIV testing use and costs under different scenarios

- identify assumptions to be used in estimation
  - demand assumptions
  - cost assumptions
- specify estimation techniques

3. Data Collection and Processing

Although the protocol specifies that data be collected from a number of sources, it is assumed that the financial responsibility for data collection activities associated with the AIDS Knowledge and Attitude Survey, the National Ambulatory Medical Care Survey, and the cost data to be collected from the alternate test sites by CDC will rest with the Federal Government. Nevertheless, it is important that an individual on the project be responsible for coordinating these collection activities with others being done in the study.

There are three data collection activities to be funded in this protocol:

- collection of cost data from labs
- collection of client waiting and travel time data at the test sites
- collection of utilization and cost data from government agencies and third parties

Each data collection activity involves four steps that must be performed for each survey:

(1) finalize and pretest the questionnaire
(2) train interviewers and coders
(3) field work
(4) data coding, data entry, and data cleaning.

4. Data Analysis

Analysis activities include conducting descriptive analyses as well as the multivariate analysis described in Chapters IV, V and VI. The analysis activities associated with Tasks 1-5 can be conducted concurrently. Tasks 6 and 7 analyses conclude after the analysis for the first 5 tasks.

5. Report Writing

The final task of the study is report writing. We recommend that separate reports be written for each task and that there be a final report summarizing the findings.

6. Time Period

The recommended time period is 30 months. We feel that this is the minimum amount of time necessary to perform all of the study tasks. It is predicated on close cooperation between the study investigators, CDC staff involved in the collection of test site data, and NCHS staff responsible for the AIDS Knowledge and Attitudes Survey and the National Ambulatory Medical Care Survey.

C. Resource Requirements

It is difficult to provide estimates of precise resource requirements at this time. These estimates depend critically on the size of the sample survey and length of time necessary to collect client and lab data and data from government agencies and third parties. We assume that costs associated with other data collection necessary for the study will be absorbed in the CDC and NCHS budgets. The costs outlined here are therefore considered preliminary. Table 12 shows our cost estimate for the project, followed by a detailed explanation of each item.

Table 12. Cost estimates for implementing the protocol

	Percent Time				
Staff	Year 1	Year 2	Year 3	Year 4	Average Annual Salary
Project Director	50	50	50	60	$100,000
Research Associate	100	100	100	100	70,000
Programmer	25	50	100	50	70,000
Statistician	10	5	5	10	70,000
Survey Design Specialist	50	20	5	5	70,000
Econometrician	10	10	25	15	70,000
Secretary	100	100	100	100	25,000
Research Assistant	50	50	50	50	30,000
Data Coder	0	80	50	0	18,000
Data Collector 1	50	100	15	0	20,000
Data Collector 2	50	100	15	0	20,000
Supplies					15,000/year
Travel					20,000/year
Computer Time					30,000/year
Communications					10,000/year
Consultants: (Epidemiologist) (Psychologist)					40,000/year

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APPENDIX A

DESCRIPTION OF CURRENT PROCESS FOR DETECTING HIV INFECTION

A. How Does HIV Infection Occur?

There is currently available a tremendous amount of information on the various modes of HIV transmission. This section briefly reviews this topic and introduces new information that is relevant to the diagnosis of HIV infection.

Infection with HIV occurs after a parenteral contact between a susceptible (uninfected) person and an infectious material. Parenteral contact for the sake of this discussion includes exposure of mucous membrane tissue, such as the vagina, rectum or urethra, to or injection of materials that contain HIV. Infection with HIV does not follow every parenteral exposure; a fraction of exposures actually results in HIV infection. The proportion of exposures that actually results in HIV infection varies with mode of parenteral contact; for example, the risk of HIV infection is greater in rectal than vaginal intercourse.

In addition to varying with mode of parenteral contact, the transmission rate of HIV varies among individuals; some HIV infected persons appear to be more infectious than others; they are the so-called high frequency transmitters (Padian, 1988). While the biologic mechanism for variability in infectiousness for HIV has yet to be determined, the implications of this phenomenon can be considered. The ability to counsel individuals at risk for HIV infection about the likelihood of infection is limited by the variability in transmission rates. For example, it would be impossible to predict precise odds that the sexual partner of an HIV infected person will become infected through vaginal intercourse; it may be the average figure of 1 in 1,000 or the high frequency rate of 1 in 2.

Infection is defined as the presence and replication of microorganisms in the tissues of the host (Brachman, 1985). The presence of infection can be determined several ways. Infection may lead to symptoms of disease, which if characteristic of the disease, can be specific enough to diagnose infection. For example, chickenpox is most commonly and accurately diagnosed on the basis of a characteristic skin rash and clinical presentation. Other illnesses cannot be accurately diagnosed on the basis of clinical manifestations. For example, a breast mass or lump may be due to a malignancy or, more often, a benign fibrocystic lesion. In this situation a diagnostic test rather than clinical presentation is used to determine the diagnosis. Clinical findings such as a breast lump are often not accurate tests for the presence of disease. Such findings are often both insensitive and non-specific for any given disease.

Sensitivity, or the probability that a diseased individual tests positive, is one way to assess accuracy of a diagnostic test (Ingelfinger, 1983). Sensitivity is a conditional probability and is defined as (T+/D+) where T+ is the number of positive diagnostic test results and D+ is the number of individuals with disease. A sensitive test is more apt to detect disease than an insensitive one. A sensitive test will not miss cases of HIV infection.

A second measure of test accuracy is specificity, or the probability that an undiseased individual tests negative (Ingelfinger, 1983). Specificity is defined as (T-/D-) where T- is the number of negative test results and D- is the number of individuals in the study population without disease. A specific test is less likely to falsely indicate disease than a non-specific one. A specific test will not find HIV infection when it is not really present.

The sensitivity and specificity are characteristics of a given diagnostic test, they do not depend on the probability of a disease within the population being tested.

By contrast, the positive predictive value of a test is influenced by the frequency of a given disease in the test population. Positive predictive value is defined by both the accuracy of a diagnostic test and the frequency of disease. The positive predictive value of a test is the proportion of positive tests that are associated with disease. Likewise the negative predictive value of a diagnostic test reflects both the accuracy of a test and the frequency of disease. The negative predictive value is defined as the proportion of negative tests that are associated with the absence of disease. In HIV testing, the positive predictive value of a test or, in other words, the chances that a positive test is not false, is much higher among high risk groups, such as homosexual men, than low risk groups like blood donors. A positive test in a heterosexual female blood donor is more apt to be a false positive than a true positive.

Diagnostic tests for infections include culture methods to detect host response to infection, and newer methods that identify the DNA or gene products of microorganisms in host tissue. All of these approaches have been applied to the diagnosis of HIV infection and a number of reliable and accurate tests are available. New types of HIV diagnostic tests are being introduced at a very rapid rate, producing difficulty for those who study issues related to HIV testing.

While all persons who are infected with HIV are potentially infectious to other, susceptible individuals, no test has been proven to predict the infectiousness of any given HIV infected person, or whether this changes over time. As mentioned previously, the infectiousness varies between individuals and over time in any single individual. At this time, no diagnostic test accurately predicts the infectiousness of an HIV infected person to others.

B. Clinical Presentation as Method of Detecting HIV Infection

Clinical presentation would be a useful diagnostic method for detecting HIV infection only if new or recent infections are reliably detected before onset of the asymptomatic phase. Onset of infection (acute infection) with HIV produces mononucleosis-like symptoms in up to 92 percent of cases identified via prospective studies of high risk populations (Tindall, 1988; Cooper, 1985; Kessler, 1987). However, other studies have not identified symptoms of acute HIV infection as frequently; Boyko and coworkers (1987) reported on recent HIV infections among participants in a prospective study of a population at high risk for AIDS. In this study, only 16 percent of 62 men with recent HIV infections reported symptoms at the time of infection, while 11 percent of 122 uninfected controls reported symptoms during the same period of time.

The studies that show a high frequency of symptoms in cases of recent infection with HIV can not, necessarily, be generalized to other populations; the studies monitored their participants very closely. Cooper and others determined that acute HIV infection was associated with fever, sweats, malaise, lethargy, anorexia, nausea, headache, sore throat, diarrhea, and skin rash (Cooper, 1985). However, these symptoms are not characteristic of or specific to HIV infection; they were present in 40 percent of an uninfected control group (Tindall, 1988).

The maximum sensitivity of the clinical presentation of acute HIV infection, calculated using the figures of Tindall and colleagues, is 92 percent, and the specificity can be estimated to be no greater than 52 percent. Therefore, the specificity of clinical diagnosis of HIV infection is unacceptable; the value of clinical presentation as a means of identifying individuals with recent HIV infection is very limited. Since the 92 percent sensitivity figure arose from data generated by prospective and time consuming evaluation, and specificity is so low, the use of clinical presentation as a means of diagnosis of HIV infection is precluded in the setting of a screening program.

C. Diagnostic Tests as Methods of Detecting HIV Infection

When infection occurs, HIV proliferates within and depletes host helper/inducer lymphocytes (a subset of white blood cells)

(Bowen, 1985). For an excellent review of the biology of HIV see the article by Gallo (Gallo, 1987). Infectious virus can be recovered from lymphocytes and grown in tissue culture (Salahuddin, 1985). When infection with HIV occurs, pieces of the viral coat and internal core circulate within the host. These viral components are called antigens and are composed of proteins or glycoproteins (a combination of protein and sugar). HIV antigens can often be detected in the blood, cerebrospinal fluid and other bodily fluids of infected individuals, particularly early and very late in the course of HIV induced diseases (Biggar, 1985; Goudsmit, 1987; Reed, 1988; Gowan, 1988).

Antigens are named by their size, which is determined by their mobility through a gel substance in the presence of an electrical charge, a process known as electrophoresis. An example of an HIV protein antigen would be p24, and the larger gp41 is an example of a glycoprotein antigen. By definition, antigens are recognized as foreign materials and are capable of stimulating the host immune system. Recognition of HIV antigens as foreign occurs shortly after infection. The first detectable immune response to HIV antigen is the production of immune globulin M or IgM; IgM is detectable in the blood within a few days of infection (Lauritzen, 1988). As the immune response to HIV progresses, IgM production decreases and stops and is replaced by the production of IgG or gamma globulin. IgG appears several weeks after HIV infection and remains present in blood indefinitely (loss of IgG to HIV in the asymptomatic stage is rare and will be discussed in the section on chain polymerase reactions). IgG is the substance that is often referred to as antibodies.

For the most part, antibodies to HIV are very specific. They are tailored to fit the shape of HIV antigens. Binding of IgG to HIV antigens distorts the antigens; when IgG binds, antigenic protein and glycoproteins present on the viral coat may be so distorted as to cause rupture of the virus, and antigenic materials in the viral core may stop functioning. Antibodies can protect the host from infection. However, viruses that reside inside cells of the host or become even more hidden through the process of latency cannot be reached or killed by antibodies.

HIV is an RNA virus--its genes are coded by RNA. Before the virus can reproduce itself or replicate, its RNA genes must be translated to DNA. This process of translation employs the viral enzyme reverse transcriptase, which is unique to retroviruses and can be detected in the lymphocytes and blood of HIV infected individuals. Once the HIV genes have been translated into DNA, the virus directs the host cell to produce the RNA, protein and glycoprotein components that make up new HIV particles.

HIV may insert a piece of its translated DNA into the host cell's genes. This viral DNA remains hidden from the host immune system, but can reappear to stimulate replication of new HIV particles at a later time. This is known as latency. The latent viral DNA can be detected using DNA hybridization techniques or gene amplification, though these techniques are more cumbersome than other techniques that detect HIV infection.

Many different diagnostic tests are used to identify HIV infection. The most frequently used tests are: antibody detection (EIA, Western blot, radioimmunoprecipitation, and immunofluorescence), viral culture, antigen detection, and gene amplification. The following text summarizes these techniques and will be followed by a brief description of the newer methods.

1. Direct Culture Tests

When HIV is placed in culture with susceptible cell lines (types of human cells that are grown in the laboratory), the replication of virus is accompanied by an alteration in the appearance of tissue culture cells (Salahuddin, 1985). The entire culture procedure can require up to 10 days (Jackson, 1987) and must be done in a facility that is certified to handle HIV.

The presence of virus in cultured cells can be confirmed using a fluorescent antibody that binds to the virus. Cells infected with the virus appear bright green under ultraviolet light microscopy (Popovic, 1984). Feorino and colleagues (1987) reported a different method--an antigen assay and a reverse transcriptase assay for the detection of HIV in culture. The antigen assay was far more sensitive and is now used routinely to confirm the results of HIV cultures (Jackson, 1989; Paul, 1987).

A positive culture of HIV is positive proof of infection. However, because the proportion of lymphocytes that are infected with HIV at any one time is small, sampling error can easily occur; blood drawn for HIV culture may not include the relatively rare HIV infected lymphocyte.

HIV culture has been utilized in clinical studies to detect infection. However, the technique is cumbersome and is considered primarily a research tool. Many reported evaluations of the other HIV tests have used culture for the purposes of comparison.

Jackson (1988) studied 142 individuals with serum antibody to HIV and recovered HIV in culture in 100 percent of 72 individuals with symptoms and in 99 percent of 70 individuals without symptoms. In a similar study, Gallo (D., 1987) reported that 83 percent of 23 symptomatic and 95 percent of 21 asymptomatic patients were culture positive; 42 antibody negative subjects were culture negative as well. However Bolton (1987) reported isolation of HIV from only 192 (47%) of 410 individuals with serum antibody to HIV. Albert reported isolation of HIV from 100 percent of 12 AIDS patients, 81 percent of 16 ARC patients, 68 percent of 22 with generalized lymphadenopathy, 26 percent of 39 asymptomatic patients all of whom had antibodies to HIV, and none of 77 without antibodies to HIV. Albert's study suggests a high degree of specificity. However, this same study recovered HIV from 85 percent of 6 individuals with the symptoms of acute HIV infection; when the symptoms resolved only 26 percent still had positive cultures, which indicates a lower sensitivity after the acute period has passed.

HIV culture is unlikely to be used as a mass screening test, rather it has been used as a gold standard for all tests due to its high specificity. Existing reports show that HIV culture can be relatively insensitive in certain laboratories. The high degree of variability between laboratories in the sensitivity of HIV culture also limits the value of the technique in diagnostic testing. A recent report confirmed interlaboratory variability in the sensitivity of HIV culture and noted plans for the establishment of standards of performance (Gold, 1988). However, the sensitivity of the HIV culture appears to have increased with time, and the method may be used as a confirmatory test if future studies produce more consistent results.

2. Antigen Detection

HIV antigens, most commonly p24, can be identified in blood and serum (the cell free or liquid component of blood). One technique for determining the presence of HIV antigens is the EIA (also called ELISA, enzyme immunoassay, enzyme linked immunoassay, antigen capture assay, immunocapture assay or solid-phase immunoassay), which is a version of the technique used to detect HIV antibodies.

The EIA method places a test blood specimen in contact with plastic beads that have been coated with human anti-HIV antibodies. The beads are then rinsed with rabbit anti-HIV antibodies, and finally goat anti-rabbit antibodies that have a color indicator attached. A color change occurs if HIV antigen is present in the test specimen; the amount of color change is proportional to the amount of antigen present. A spectrophotometer is used to precisely measure the degree of color change.

Several manufacturers produce HIV EIA antigen detection kits; these include Abbott (Abbott Manufacturing Corporation, North Chicago, Illinois), Cellular Products (Buffalo, New York), duPont (E.I. duPont de Nemours & Company, Wilmington, Delaware), and Coulter (Coulter Immunology, Hialeah, Florida). Many research laboratories use their own antigen detection EIA tests.

The EIA test usually takes about 4 hours, and its estimated cost is $5.50 per test (personal communication with Coulter Corporation).

The accuracy of the antigen assays has been assessed in several studies. One study noted that an antigen EIA test was 10^2 to 10^3 more sensitive than an assay for reverse transcriptase activity in *in vitro* testing (Paul, 1987). Paul also reported the results of antigen tests of tissue culture cells that were not infected with HIV; all HIV antigen tests were negative, suggesting a high degree of specificity *in vitro*.

The presence of HIV antigens in the blood or serum is diagnostic of HIV infection, and may have negative prognostic value. As previously mentioned, HIV antigens can be found in blood shortly after infection. Bowen and colleagues (1988) described the transmission of HIV from the donor of a transplanted kidney to the recipient. The transplant recipient was followed with regular HIV antigen and antibody determinations, T-lymphocyte counts and clinical evaluations. Figure A-1, taken from Bowen's paper, demonstrates a representative time course of HIV antigenemia and development of antibody. Antigen was detectable in blood immediately after the transplant; antigen levels peaked between days 10 and 22 posttransplant. The decrease in antigen after day 22 was proportional to a rise in serum antibody; this is consistent with the removal of free antigen through binding to antibody (Goudsmit, 1987).

Free serum HIV antigen can be present later in the course of infection and is also associated with lower levels of serum antibody (see figure A-2); in this setting, low levels of antibody are probably due to reduced production that occurs in the terminal stages of AIDS (Pedersen, 1987).

Several studies have described increasing amounts of HIV antigen with progression from the asymptomatic phase to ARC and AIDS (Paul, 1987; Allain, 1987; Goudsmit, 1987; Lelie, 1988; de Wolf, 1987). Paul and others (1987) reported a study of serum antigen levels in HIV antibody positive individuals (determined by EIA and Western blot); 19 percent of asymptomatic individuals, 46 percent of patients with ARC, and 69 percent of patients with AIDS had positive serum HIV antigen tests ($p<.0001$ by x^2). In a similar study, Lelie and associates (1988) determined that 5 percent of symptom free, 19 percent of ARC, and 46 percent of AIDS patients had positive serum tests for HIV antigens. de Wolf (1987) reported that 2 (1.4%) of 138 antigen negative men and 11 (18%) of 60 antigen positive men developed AIDS ($p<.00001$).

The accuracy of HIV antigen assays can be measured using two approaches: 1) assessment of accuracy in the detection of

Figure A-1. Comparison of HIV antibody and antigen levels over time

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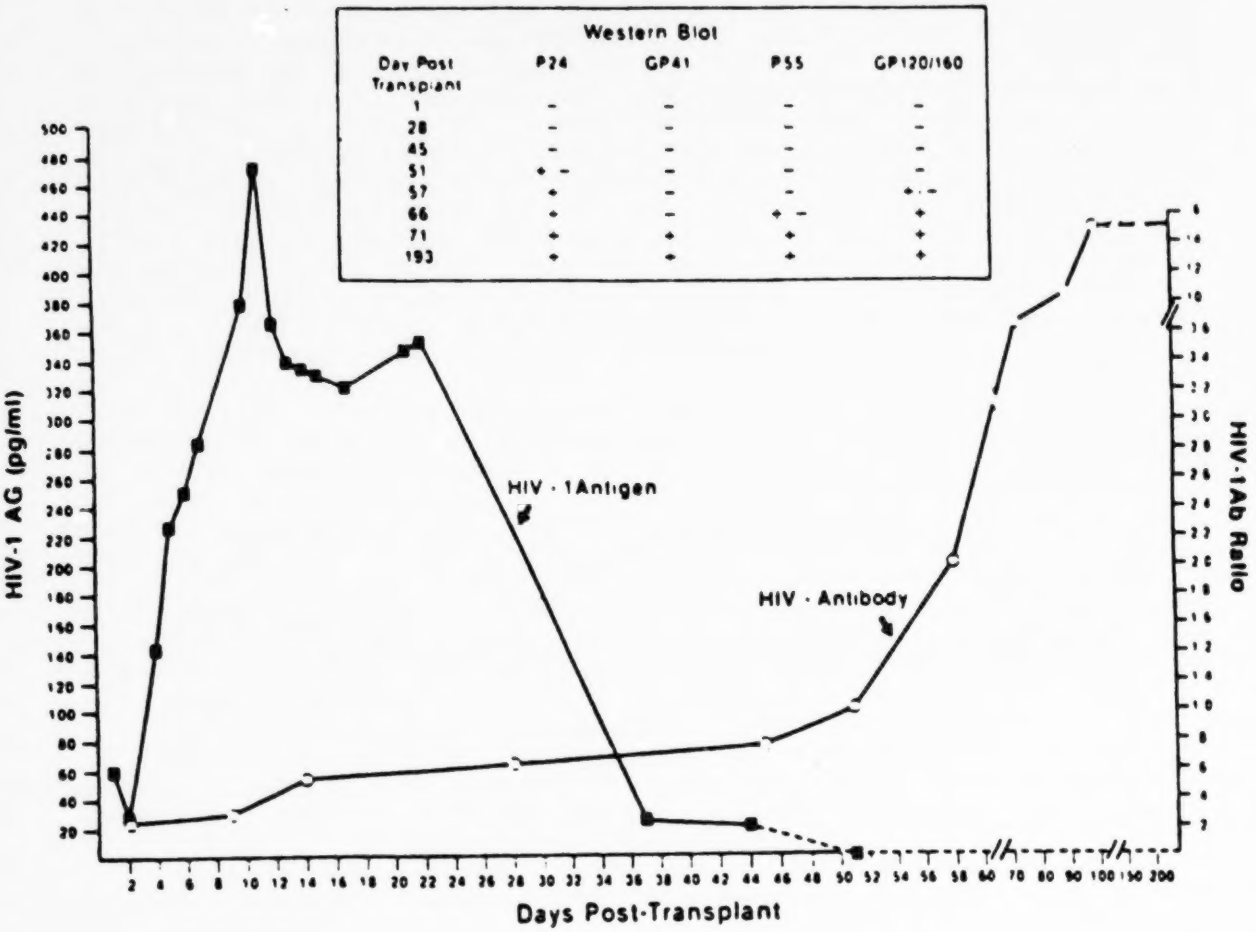


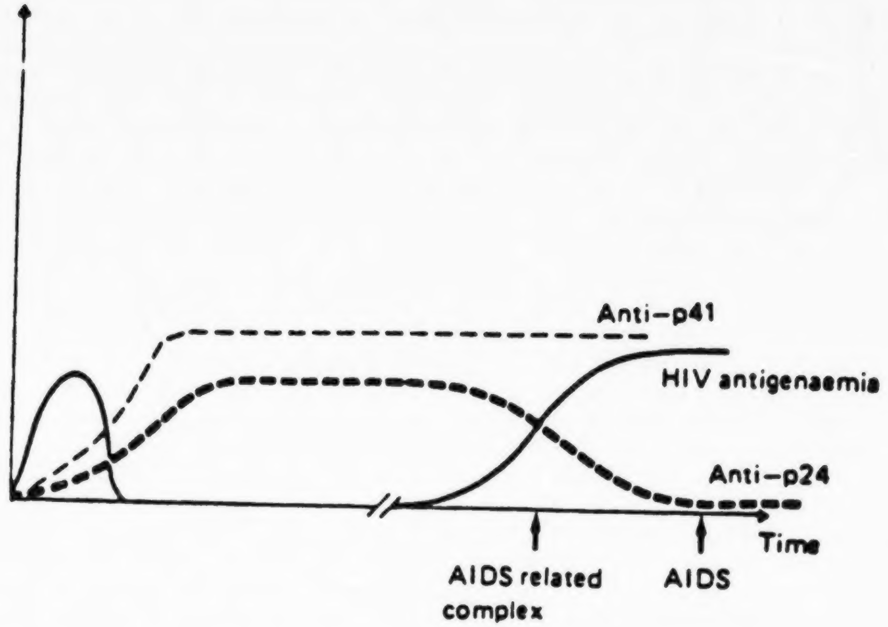
Western Blot

Day Post Transplant	P24	GP41	P55	GP120/160
1	−	−	−	−
28	−	−	−	−
45	−	−	−	−
51	+ −	−	−	−
57	+	−	−	+ · −
66	+	−	+ −	+
71	+	+	+	+
193	+	+	+	+

Human immunodeficiency virus (HIV) antigen (AG), antibody (Ab), and Western blot results. Open circles show HIV-1 antibody (signal to noise ratio). Black squares show HIV-1 (p-24) antigen (pg/ml). Western blot analyses were qualitatively interpreted as compared to a weak reactive control for intensity and to a strong reactive control for molecular weight determination.

Source: Bowen, P.A., S.A. Lobel, R.J. Carauana, M.S. Leffell, M.A. House, J.P. Rissing, A.L. Humphries. Transmission of Human Immunodeficiency Virus by Transplantation: Clinical Aspects and Time Course Analysis of Viral Antigenemia and Antibody Production. Annals of Internal Medicine, 103:704-709, 1988.

Figure A-2. Serological profile of HIV infection



Source: Pedersen, C., C.M. Neilsen, B.F. Vestergaard, et al. Temporal Relation of Antigenaemia and Loss of Antibodies to Core Antigens to Development of Clinical Diseases in HIV Infection. British Medical Journal, 295: 566-569, 1987.

early or primary infection (when antibody assays are more likely to be negative), or 2) detection of HIV infection during any stage of illness.

Data is scanty on the proportion of positive antigen tests in seroconverters (individuals in whom, HIV infection is documented by a transition from negative to positive serum HIV antibody tests). Kessler and coworkers (1987), found that 100 percent of a group of 4 seroconverters were positive for HIV antigen in blood samples taken during an illness that clinically resembled acute HIV infection. Positive antigen tests were present in 14 percent of 58 seroconverters studied by deWolf (1987) and 33 percent of a population of 39 seroconverters and patients with clinically defined acute HIV infection studied by Lindhart (1988). In a report by Busch and colleagues (1988), only 1 (3%) of 32 seroconverters had a positive antigen test at the time of the first positive serum antibody test.

In the studies mentioned above, HIV antigen was never detected in persons who did not eventually acquire serum antibody to HIV or have positive HIV cultures, which suggests a low rate of false positive results. Bäcker (1987), however, reported the results of a blood donor screening program that utilized antigen testing as well as antibody assays; 253 (0.17%) of 152,099 blood donors had repeatedly positive antigen tests and negative assays for serum antibody. These results indicate that rare false positive HIV antigen tests do occur, and that studies of the specificity of antigen tests must have very large populations to have adequate power.

Antiviral medications may affect the results of antigen tests. Chaison and colleagues (1986) reported that HIV antigen levels decrease in AIDS patients after AZT treatment.

Several conclusions on the use of antigen detection tests for HIV infection can be drawn from existing studies:

* A positive antigen test (HIV antigen in blood) is often present early after HIV infection, before serum antibodies develop

* A positive antigen test may recur late in the time-course of HIV infection

* The recurrence of HIV antigen often coincides with a decrease in serum antibody levels

* A positive antigen test outside the earliest stages of infection may suggest immunologic dysfunction and may have prognostic implications

- Some patients with a positive antigen test remain well for long periods of time

- Many asymptomatic ARC and AIDS patients have negative antigen tests

- HIV antigen is not detected consistently prior to seroconversion

- Medications may impair antigen detection

These points provide the limitations of antigen testing for the detection of HIV infection. Sensitivity in the clinical setting is low, although specificity is greater than 99 percent (no false positive tests have been reported). While HIV antigen tests may be of limited value in detecting infection, they may have a role as prognostic indicators, or in screening under special circumstances.

3. Detection of anti-HIV Antibodies

a. Enzyme immunoassay (EIA)

The first method for the detection of antibodies to HIV was the EIA test reported by Sarngadharan in 1984. The test was designed as a tool for screening donated blood. In March, 1985 the Food and Drug Administration (FDA) approved, for the screening of donated blood, EIA test kits manufactured by Abbott Laboratories, Electro-Nucleonics (Farifield, New Jersey), and Litton (Litton Bionetics, Charleston, South Carolina).

EIA tests detect anti-HIV antibodies (usually IgG) in small samples of blood or other body fluids. The procedure involves coating a plastic surface with HIV antigens, which are usually extracted from infected tissue culture cells. A test specimen is placed in contact with the plastic surface, which permits the binding of any anti-HIV antibody (if present) to HIV antigen. The test specimen is rinsed off the plastic and replaced with anti-human IgG antibody of animal origin that is linked to a color producing substance; the animal antibody will bind to the human anti-HIV antibody if it is present on the plastic surface. Excess animal antibody is rinsed off the plastic surface and replaced with a chemical that will react with the color producing substance; a color change occurs if the test specimen contains anti-HIV antibodies, the intensity of color is proportional to the amount of antibody present (Council on Scientific Affairs, 1985). Currently available EIA tests are listed in table 2 (section I) with specificities and sensitivities.

The commercial EIA tests take up to 2 hours to run, and require the use of a spectrophotometer, which may prevent use of the test in developing countries, physician offices, emergency rooms and other settings. The EIA is a relatively inexpensive test, (most kits cost less than $5.00 per test) though this cost may be prohibitive in some countries and significant in any setting in which large numbers of specimens are screened. Recently several investigators have reported use of pooled sera to reduce the cost of screening large populations; this approach has the greatest potential in the screening of low prevalence populations (Hernandez-Avila, 1988; Quinn, 1988).

b. False negative test results using EIA

Positive EIA tests are highly predictive of illness related to HIV, and negative tests may occur in the case of AIDS. In 1984 Brun-Vezinet reported the use of an EIA test to detect serum antibodies to HIV; positive results were found in 1 (1%) of 100 blood donors, 8 (18%) of healthy homosexual men, 38 (75%) of 51 patients with generalized lymphadenopathy and 18 (38%) of 48 AIDS patients. Weiss and colleagues (1985) reported positive EIA tests in 84 percent and 78 percent of two groups of AIDS patients, 53 percent of homosexual men and 46 percent of IV-drug users. Two percent of blood donors in Vermont and less than 1 percent of laboratory workers in New York and Maryland tested positive. Figure A-2, taken from Pedersen (1987), demonstrates the loss of anti-HIV antibody that occurs late in HIV infection, often in association with recurrence of antigenemia. In Pederson's study, 12 of 256 subjects who were initially EIA positive became negative for antibody to the p24 antigen; loss of this antibody was associated with the development of AIDS. Groopman and colleagues (1985) found negative HIV EIA, IFA, RIPA and Western blot tests in 2 patients, one AIDS case and one generalized lymphadenopathy; both men had positive HIV cultures. EIA methods may lack a degree of sensitivity in very ill AIDS patients. However, since EIA testing is more often employed in the detection of HIV infections in individuals who are not already known to have HIV related diseases, insensitivity in end-stage disease is not a great problem.

Insensitivity early in HIV infection is more problematic. Serum antibodies to HIV are not present immediately after infection, which may be a cause of false-negative results (inherent in the approach of testing by detection of antibodies). Figures A-1 and A-2 demonstrate the lag period between HIV infection and development of anti-HIV antibodies. As mentioned previously, the first anti-HIV antibody produced after infection is IgM that is not detected by the IgG EIA kits currently in use in the U.S. These EIA tests will remain negative after HIV infection until production of IgG. In a study of 20 men with symptomatic acute HIV infection, Gaines and coworkers (1987) reported positive EIA tests 2 to 7 weeks after onset of illness.

In this study, the duPont EIA kit was more sensitive than Abbott, Organon Teknika, Elavia, and Wellcome; all but one sera obtained 15 days or later after onset of illness were reactive. By contrast, 5 of 5 subjects had positive HIV cultures taken on day 8 after onset of illness. Results using immune fluorescence (IFA), radioimmunoprecipitation (RIPA), and Western blot (WB), however, were comparable to EIA; the first positive tests occurred at 2 weeks.

False negative EIA tests have resulted in transmission of HIV to transfusion recipients. Ward and colleagues (1988) identified 12 blood recipients who acquired HIV infection after receiving blood that tested negative to HIV by EIA, apparently all 7 donors had early HIV infection and had not yet developed serum IgG antibodies to HIV at the time of blood donation.

c. False positive test results using EIA

Despite the inherent limitations of sensitivity in early HIV infections, the EIA technique has been considered the backbone of HIV screening programs such as the blood bank program (Goedert, 1986). In a study of blood donors, the CDC reported a specificity of 99.8 percent; sensitivity was estimated at 97 percent (Ward, 1986). In that study, the proportion of culture positive subjects was compared by the depth of color change produced in the assay; Ward found that the greater the color change the greater the chances that HIV culture was positive. Weiss (1985) calculated the sensitivity and specificity according to color change in EIA tests and demonstrated that in general specificity sacrifices sensitivity and vice versa; the lowest amount of color change resulted in a specificity of 97.7 and a sensitivity of 92.6, the greatest amount of color change in 96.6 and 99.3 respectively. Thus, the amount of color change that is selected as the cut-off for a positive EIA test is subjective; a low cutoff (a specimen producing relatively small amount of color change is considered positive) may be used in blood banking where a false negative test may result in the transmission of HIV to a blood recipient, or a high cutoff may be selected in a setting where the prevalence of HIV infection is expected to be relatively low and the outcome of ar false positive test would be adverse, such as in prenatal screening of low risk women.

It has been proposed that use of a high cutoff for positive EIA tests may eliminate false positive tests and therefore the indication for confirmatory testing. Cable and others (1986) with the American Red Cross blood program followed up 91 blood donors who had positive EIA but negative Western blot tests; on repeat testing only 17 (19%) were still EIA positive and those that were positive were more apt to have had a strongly positive test initially ($p<.05$). However, Martin and coworkers (1986) found that the degree of EIA reactivity is not a sufficient indicator of the presence of HIV infection; they reported that 5 percent of specimens with the highest degree of color change were not positive in a Western blot confirmatory test.

The impact of false positive EIA results varies with the prevalence of true HIV infection in the population to be tested. The prevalence of HIV infection in the general population, such as that seen among blood donors, means that the majority of positive tests will be false even though the accuracy of EIAs is very high and compares favorably with many other diagnostic tests. If a given EIA test has a sensitivity of 98.9 percent and a specificity of 99.2 percent, the percentage of false positive tests would be 89 and 44 given a true prevalence of HIV infection of 0.1 percent and 1.0 percent respectively (Council on Scientific Affairs, 1985). Table 1 (section I) lists the positive predictive value of an EIA test with a sensitivity and specificity of 95 percent (Lundberg, 1985). The CDC estimated the performance of Abbott, Electronucleonics and Litton EIA tests, based on a prevalence of true HIV infection of 250/100,000, and found an average positive predictive value of 8.4 and negative predictive value of 99.9 (Taylor, 1988). Meyer and Pauker have questioned the wisdom of applying the HIV EIA as a tool for screening very low prevalence populations (Meyer, 1987).

False positive test results may not be inherent in the EIA methodology. Many false positive EIA tests are due to cross-reactions with impurities in the relatively crude H9 preparations. Some individuals, in particular young women, have antibody that reacts with the H9 cells in which HIV is grown. Cross-reacting antibodies to human leukocyte antigens (HLA groups) have been identified in young women and in up to 6 percent of dialysis patients (Fassbinder, 1987; Arno, 1988). Several groups have reported promising results with EIA tests that use HIV antigen that is derived from recombinant DNA rather than H9 cells. Burke (1987) reported that an EIA that employed a recombinant HIV envelope polypeptide was superior to Western blot in detecting the anti-HIV antibody (sensitivity 99.9 and specificity 99.1). Schneider (1987) also reported the improved accuracy of an EIA test based on a highly pure recombinant HIV transmembrane glycoprotein. Hellings and coworkers (1987) adapted a commercial EIA test by adding a reagent that blocks anti-H9 antibodies, and reported a sensitivity of 100 percent and a specificity of 98 percent in comparison to Western blot; not a drastic improvement. Several other investigators have produced EIA tests with increased accuracy by the use of competitive binding techniques and recombinant proteins (see table 3, section I).

In summary, the EIA test is:

* Very sensitive and specific compared with other diagnostic tests

* Inexpensive, simple to perform and rapid relative to other HIV diagnostic tests

* Relatively insensitive in early infection, as is any test that detects antibody to HIV

* Less sensitive in very late infection than during the asymptomatic phase

* By far the most common test used for the detection of HIV infection

* Modifiable, such that may it be improved in future test kits

The incidence of false positive EIA tests continues to be unacceptably high, particularly in very low prevalence populations. Continued HIV diagnostic testing of these populations is mandated by the needs of the blood banking industry, the policy of the U.S. military and the personal choices of many individuals who appear to be at low risk for HIV infection. Thus, most positive EIA tests are confirmed by another test that employs different technology, such as the Western blot or the IFA.

d. Western blot

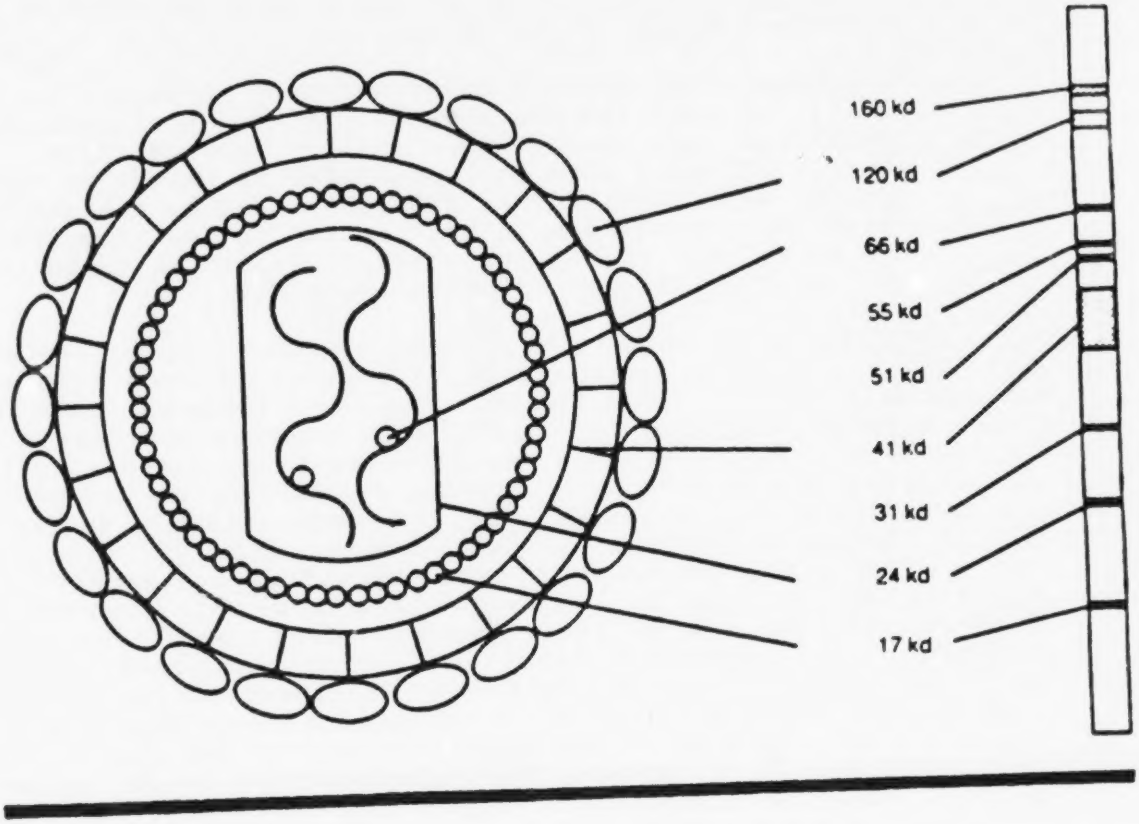
The Western blot (WB) test has greater specificity than the EIA and is currently considered the "gold standard" confirmatory test for serum antibodies to HIV (Consortium for Retrovirus Serology Standardization, 1988). Its greatest disadvantages are that it is a cumbersome laboratory procedure, and currently only one manufacturer produces commercial reagents for the test, although many laboratories utilize their own Western blot procedures and reagents. This has resulted in a lack of standardization of testing procedures.

The Western blot test is performed in five stages:

1. HIV viral protein and glycoproteins are purified using virus grown in tissue culture.

2. The purified proteins and glycoproteins are separated into bands according to molecular weight by flowing them through a gel material with an electrical charge. The distribution of proteins within the gel is unique to HIV (see figure A-3).

Figure A-3. Illustration of human immunodeficiency virus components by Western blot analysis


160 kd
120 kd
66 kd
55 kd
51 kd
41 kd
31 kd
24 kd
17 kd

kd = kilodaltons

Source: Consortium for Retrovirus Serology Standardization. Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing. JAMA, 260: 674-679, 1988.

3. The proteins are transferred from the gel material to paper-like nitrocellulose strips.

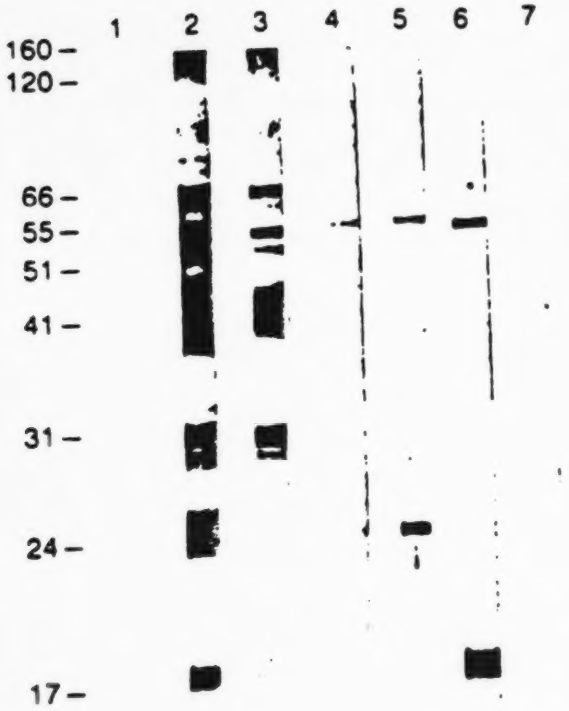
4. The nitrocellulose strips are soaked in serum from the test recipient's blood to allow anti-HIV antibody to bind to HIV proteins and glycoproteins, then unbound serum antibody is rinsed off the strips, anti-HIV antibody remains on the strips.

5. A chemical that detects human antibody is placed on the strips, if anti-HIV antibody is present, the bands on the strips that contain this antibody change color. Since the HIV proteins have been separated by weight on the strips, bound antibody is also separated by the molecular weight of the antigen it has reacted to (see figures A-3 and A-4). Therefore, the pattern of colored bands should be characteristic of infection with HIV.

The preceding paragraph reviews the most basic aspects of the Western blot technique, many variations of each step exist. In addition to procedural variations, the reagents used differ greatly among laboratories that provide Western blot tests. The variability in technique and reagents produces variability in the accuracy of tests. The most crucial reagent in the WB procedure is the antigen preparation, in the case of HIV testing the protein and glycoprotein material derived from HIV grown in H9 cells. Analogous to the EIA test, impurities in the HIV antigen reagent can result in false positive or uninterpretable WB results. Because the WB procedure separates impurities from HIV antigens, false-positive reactions occur less frequently than with EIA. A low concentration of antigens or an inadequate preparation can result in false negative or uninterpretable test results. As a result of the proven impact of the quality of HIV antigen reagents on Western blot confirmitive tests, guidelines have recently been devised to ensure the uniformity and adequacy of this reagent (Consortium on Retroviral Testing, 1988). Improvements in the quality of the HIV antigens used in WB procedures should improve with the application of techniques such as recombinant DNA methods. Schultz and colleagues in Austria (1986) reported use of a set of recombinant HIV proteins and glycoproteins in the WB procedure; no false positive results were obtained from 251 specimens, and the recombinant WB detected antibodies in a preterminal AIDS patient who had negative IFA and conventional WB tests.

The interpretation of Western blot test results also can vary; if 1 or 2 bands are present on a Western blot is it positive? The results of this kind of decision are crucial, the potential harm of misinterpreted tests is enormous. Therefore, the Consortium for Retrovirus Serology Standardization has devised criteria to guide interpretation of Western blot test results. A blot with stained band at p24 or p31 and gp41 or

Figure A-4. Western blot tests from various donors



Lane 1: Human immunodeficiency virus Western blot tests of serum from nonreactive donor.
Lanes 2 & 3: Patients with acquired immunodeficiency syndrome.
Lane 4: Early seroconverter.
Lanes 5 - 7: healthy donors with nonspecific human immunodeficiency virus reactivity.

Source: Consortium for Retrovirus Serology Standardization. Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing. JAMA, 260: 674-679, 1988.

gp120/gp160 will be considered positive. A truly negative test has no bands stained at all, those tests with stained bands but not meeting criteria for a positive blot are considered indeterminate. Package instructions for the DuPont WB kit requires, for the identification of a positive test, the presence of antibodies two three different groups of HIV antigens (Medical Letter, 1988). The CDC has pointed out that these criteria may be too restrictive and result in false negative interpretations (CDC, 1988).

Despite an effort to standardize interpretation of Western blot tests, six groups have proposed differing sets of interpretation criteria; the Food and Drug Administration, the Department of Defense, the American Red Cross, the Public Health Service consultative group, the Association of State and Territorial Public Health Laboratory Directors, and the Consortium for Retrovirus Serology Standardization. A unified and standardized approach to the interpretation of WB results would go a long way towards defining the meaning of WB test results.

Resnick and Shapshak studied 674 individuals with HIV infection; 100 percent of 305 AIDS and ARC patients, and 96 percent of 208 asymptomatic individuals had positive tests for gp41 antibody. In the same study none of 5 individuals with acute HIV infection (as determined by clinical criteria) had anti-gp41 antibody present, however all 5 has antibody to p24. After acute infection, antibody levels increase with time so that later retesting of recipients of equivocal WB results may yield positive test results (Esteban, 1985).

If stringent criteria are applied to the interpretation of WB tests, false negative results in early HIV infection will be inherent in the method. The value of Western blot testing is a higher degree of specificity than EIA testing. If stringent criteria are not applied to the interpretation of WB results false positive readings can occur (Couroucè, 1986).

In general the Western blot test is:

* Subject to variability in interpretation

* More specific than EIA if stringent criteria are applied to test interpretation

* More sensitive than EIA in early HIV infection if stringent criteria are not applied

* An expensive, time consuming, and cumbersome laboratory procedure

- The most commonly used confirmatory test
- Likely to become less variable with the development of new reagents and standardization of the procedure

e. Immunofluorescence (IFA)

The IFA test is used as a confirmatory test for HIV infection. Like the EIA and the WB, the IFA detects the presence of anti-HIV antibodies. The test procedure involves fixing HIV infected H9 cells on glass microscope slides. A small test specimen of blood is placed on the slide and incubated, allowing any anti-HIV antibody that is present to bind to the HIV infected cells. The slide is rinsed and a solution of anti-human antibody that is attached to a fluorescent marker is placed on the slide; if anti-HIV has bound to the cells, the fluorescent marker will also bind. Finally, the slide is examined under a fluorescent light microscope. If anti-HIV antibody is present in the test specimen, the outline of the H9 cell will glow a bright green (Sandstrom, 1985).

Sandstrom found that 94 percent of sera from patients with AIDS, 88 percent of sera from patients with lymphadenopathy, and 50 percent of sera from asymptomatic homosexual men were positive by IFA. The results of IFA tests were virtually identical to Western blot in this study (Sandstrom, 1985). van der Groen and colleagues (1987) calculated the sensitivity and specificity of three IFA tests in comparison to immunoblot; the IFA tests ranged from 81 percent to 100 percent sensitive, and 87 percent to 100 percent specific. Carlson and coworkers (1987) reported that IFA and WB were in 100 percent agreement when compared using specimens from AIDS patients, however there was only an 89 percent correlation between IFA and WB when the tests were employed in screening donated blood.

In general IFA tests:

- Have similar accuracy to Western blot
- Like WB, the procedure is variable
- Are slightly subjective; microscopy and determination of result must be standardized and done by an experienced technician
- Are inexpensive once initial equipment is available, but relatively time consuming

Currently no IFA has been licensed, though many laboratories employ the test using reagents and procedures that may be unique to their setting. IFA methods are frequently employed in diagnostic laboratories in kit form; therefore, a commercial IFA kit for the detection of HIV infection is a likely development.

f. Radioimmunoassay

Radioimmunoassay (RIP, or RIPA) is also used as a confirmatory test for the detection of HIV infection. In brief, the RIPA procedure involves labelling HIV infected cells (from tissue culture) with a radioactive marker. The radioactive cells are broken up and the material is mixed with a test serum specimen and incubated for several hours to allow anti-HIV antibodies, if they are present, to bind to radioactive HIV antigens in the cell mixture. The immune complexes made up of antibody and radioactive antigen are separated out and the radioactivity is measured with a geiger counter-like device. Radioactivity is proportional to the amount of antibody in the test specimen (Resnick, 1985; Chiodi, 1987).

Resnick reported in 1987 that RIPA produced similar results to WB when employed in a panel of 678 sera. Chiodi (1987) found that results of the two tests were similar, though RIPA produced fewer false positives.

In summary RIPA tests:

* Are similar in accuracy to Western blot

* Are a common research tool

* Utilize radioactive reagents, and therefore are a troublesome test procedure

* Are not currently available as commercially prepared kits

It is unlikely that RIPA will be used in large scale testing programs because other tests that have similar accuracy are available and RIPA tends to be more cumbersome. RIPA will continue to be a test that is used to assess the value of other tests.

g. Gene amplification

Gene amplification or polymerase chain reaction (PCR) is a new high tech test that detects the presence of HIV DNA within host DNA. The technique has the theoretic advantage of identifying latent infection in individuals who do not make anti-HIV antibody.

The PCR procedure involves the vast multiplication of small pieces of DNA that match up with the known sequence of HIV DNA. PCR utilizes recombinant DNA technology and is currently in development as a commercial HIV diagnostic kit (Marx, 1988). The test takes about three hours to perform and currently costs about $135.00.

Ou and colleagues (1988) reported that 100 percent of DNA specimens from homosexual men with positive EIA and culture tests were PCR positive; none of the specimens from an EIA and culture negative group were PCR positive. However, PCR was positive in only 64 percent of a group of EIA positive, culture negative homosexual men.

In a recent report Farzadegan and colleagues (1988) described four participants of a prospective cohort study of homosexual men who reverted from HIV antibody positive to negative. Unlike previous reports of loss of anti-HIV antibody, the negative antibody tests were not accompanied by the development of AIDS or ARC, and Western blot, antigen and culture tests also were negative. Thus, the four men did not have HIV infection detectable using four standard diagnostic tests, nor were there symptoms or other indications of HIV infection. A PCR test was positive in all four men. It is not known whether this report reflects a recovery from HIV infection or the occurrence of potentially transmissible latent infection. Zuck, (1988) in an editorial that accompanied the Farzadegan report, raised the issue of whether PCR tests should be applied to donated blood routinely. Clearly much more information is necessary before that determination can be made.

In review, PCR is:

- An expensive test that utilizes recombinant DNA technology
- May detect latent HIV infection that other tests fail to detect, the clinical significance of which is not known
- Will soon be available in a commercially prepared kit
- May be a useful confirmatory test or a new first-line screening test

h. Additional diagnostic test methods

New test methods for the detection of HIV infection are listed in table 3 (section I) with information on sensitivity, specificity and comments. Many of the new tests are versions of tests that are currently available. The new tests can be evaluated by the advantages they provide over previous tests:

1. Simplification of laboratory technique and/or less equipment required. This group includes passive hemagglutination, particle agglutination, and AGEN tests. Some of these test are less sensitive and

specific than the tests currently used. These tests have the most utility in the developing world and settings in which a rapid and simple test is needed and where accuracy is not essential, such as in emergency situations.

2. Simplification of specimen collection. Paper spot tests utilize EIA or WB methodology with blood specimens collected on filter paper from fingerprick rather than venepuncture that is more cumbersome. The sensitivity and specificity of the EIA or WB is not altered. This method permits specimen collection in the home, without the assistance of medical professionals and eases collection from young children.

3. Rapid. The fiber optic test and membrane binding are both quick tests with high accuracy.

4. More accurate. Competitive enzyme immunoassays may be more sensitive and specific than other EIAs and appear to be comparable to the Western blot in accuracy. The tests may have a role as confirmatory procedures (Dawson, 1988; Tedder, 1987).

These tests are examples of the kind of innovations that can occur using currently existing test technology.

D. Limitations of Existing Tests

Tests for the detection of HIV infection that are currently available have several inherent limitations. Lack of sensitivity early in infection and in terminal disease have been discussed in the preceding sections on detection of anti-HIV antibodies. Two additional situations in which currently licensed anti-HIV tests may be relatively insensitive are in the case of newborn infants and gamma globulin recipients.

Gamma globulin antibodies can cross the placenta and therefore can be transferred from maternal blood to fetal blood. It is impossible to distinguish whether gamma globulin anti-HIV antibodies are of maternal or fetal origin. Therefore, it is impossible to say, at the time of birth, whether the newborn child of a woman who has gamma globulin anti-HIV antibodies is infected with HIV based upon the currently licensed test. HIV infection in the newborn can be identified through several approaches:

- EIA and Western blot tests can be performed after a waiting period of 4-12 months. During this period maternal antibody disappears, and any antibody present after that time is the infant's (Peckham, 1987).

- Tests that detect IgM antibodies can be used. IgM does not cross the placenta, so any anti-HIV IgM present in a newborn's blood must be of infant origin (Pyun, 1987).

- HIV antigen or culture can be performed. Recovery of the virus or viral antigens from a newborn strongly supports a diagnosis of HIV infection.

The gamma globulin that is commonly given to patients who have been exposed to hepatitis A does not contain live HIV, but it may contain anti-HIV antibody. Injection of gamma globulin in the last month of pregnancy may cause false-positive HIV antibody tests (Wood, 1986).

E. Emerging Trends in Testing

New developments in HIV testing could permit in-home testing. Home testing could arise in two ways. Fingerstick specimens (obtained by sticking a finger with a sharp needle and absorbing the resultant drop of blood on a piece of paper) can be mailed to laboratories for testing. Another approach that would permit in-home testing is urine antigen testing, a more distant possibility. HIV antigens may be released into the urine and home tests, similar to pregnancy tests, could be developed to allow detection of HIV antigens in urine through an extremely simple procedure.

In-home may offer advantages in privacy and freedom from coercion, however the counseling of HIV test recipients that is considered vital to any testing program cannot be ensured with home tests. In addition, the accuracy of in-home test is likely to be no better and potentially much worse than tests performed through the larger testing centers. The psychologic implications of HIV testing and the potential harm of testing without quality assurance or counseling must be weighed against the public interest and privacy of home testing.

F. Surrogate Testing

Surrogate testing can be defined as the use of diagnostic procedures that detect conditions that are associated with either HIV infection (such as an impaired immune system) or risk factors for HIV infection (such as male homosexuality or IV-drug abuse). Surrogate testing may be used instead of direct tests for HIV infection because of legal and ethical limitations on the use of the HIV tests. Surrogate tests take advantage of epidemiologic information on conditions that are associated with AIDS, or the behavioral risk factors for HIV infection.

Many tests can be used as surrogates. Demographic information such as age, gender and marital status, medical history such as rectal gonorrhea or hepatitis related to IV drug abuse, and a large list of diagnostic tests that may detect conditions that are common among homosexual men, IV drug abusers, hemophiliacs and other high risk individuals are all possible surrogate tests. Some of these tests are listed in table 4 (section I).

T-helper cell counts (THCC) have received the most attention as surrogate tests. The T-helper cell is the type of lymphocyte (a white blood cell) that the AIDS virus destroys. As the duration of HIV infection increases, the average T-helper cell count decreases. The normal range of T-helper cell counts varies between laboratories. At the University of California, San Francisco, T-helper cell counts of 450-1100 are considered normal. The THCC can fall during any viral illness including colds. However, a count below 400 in an HIV infected person has been reported to be predictive of AIDS (Boyko, 1986; Boyko, 1987). In a study of recent seroconverters, Boyko (1987) found that T-cells did not change significantly at the time of HIV infection, and the ratio of T-cell counts declined with duration of HIV infection with marginal significance; the ratio was more sensitive to the duration of HIV infection than T-helper cell counts alone. In a study of homosexual men infected with HIV, Boyko (1986) found that the THCC was 84 percent sensitive as a test for AIDS and 70-81 percent specific for an AIDS related condition. The sensitivity and specificity of abnormal THCC or T-cell ratios is likely to be much less in lower risk populations.

In conclusion, surrogate tests for HIV infection are:

- Potentially large in number and varied, ranging from laboratory tests to questions about medical history or demographic. Because of this, regulation of surrogate tests may be very difficult to achieve

- Much less sensitive and specific than the direct HIV tests, and thus use of surrogate tests will produce many false positive and negative results

APPENDIX B

TEST SITE REPORTING REQUIREMENTS INSTITUTED BY CDC (MAY, 1988)

Department of Health & Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Atlanta, Georgia 30333

Form Approved
OMB No. 0920 0203

HIV COUNSELING AND TESTING DATA - NUMBER POSITIVE

YEAR ____ QUARTER ____

Age Group (years)	White		Black		Hispanic		Asian/Pacific Islander		Am Indian/ AK Native		Race Undetermined	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
< 5												
5-12												
13-19												
20-29												
30-39												
40-49												
50 +												
Unk												
TOTAL												

Project Area Reporting

Approved by: Title Date

CDC This report is authorized by law (Public Health Act, 42 USC 241(a)), and is required as a condition
Rev. of the Cooperative Agreement. Due date is 30 days after the end of each quarter.

Department of Health & Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Atlanta, Georgia 30333

Form Approved
OMB No. 0920 0203

HIV COUNSELING AND TESTING DATA - NUMBER OF TESTS PERFORMED

YEAR ____ QUARTER ____

Age Group (years)	White		Black		Hispanic		Asian/Pacific Islander		Am Indian/ AK Native		Race Undetermined	
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female
< 5												
5-12												
13-19												
20-29												
30-39												
40-49												
50 +												
Unk												
TOTAL												

Project Area Reporting

Approved by: Title Date

CDC This report is authorized by law (Public Health Act, 42 USC 241(a)), and is required as a condition
REV of the Cooperative Agreement. Due date is 30 days after the end of each quarter.

Department of Health and Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Atlanta, Georgia 30333

FORM APPROVED
OMB NO.
EXPIRATION

HIV Counseling and Testing Data

Year ____ Quarter ____

Groups at Risk

Groups at Risk	Number Tested	Number Positive
Homosexuals/Bisexuals		
IV Drug Users		
Homosexual/Bisexual IV Drug Users		
Blood Recipients, 1978-1985		
Persons with Hemophilia		
Heterosexuals		
Others		
Unknown		
TOTAL		

OF THE ABOVE RISK GROUPS, HOW MANY SEX PARTNERS WERE:

Sex Partners at Risk	Number Tested	Number Positive
Female Sex Partners of Bisexuals		
Sex Partners of Persons with AIDS/+HIV		
Sex Partners of IV Drug Users		
Sex Partners of Other		
TOTAL		

____
Project Area Reporting

Approved by: ______________________
Title: ______________________
Date: ______________________

CDC This report is authorized by law (Public Health Service Act, 42 USC
REV. 241(a)), and is required as a condition of the cooperative agreement
Due date is 30 days after the end of each quarter.

Department of Health & Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Atlanta, Georgia 30333

Form Approved
OMB No. 0920 0208

HIV COUNSELING AND TESTING DATA

YEAR ____ QUARTER ____

ACTIVITIES BY SITE TYPE

TESTING SITE TYPE	NUMBER OF SITES	NUMBER OF PATIENT VISITS	# PATIENTS PRETEST COUNSELED	NUMBER OF PATIENTS TESTED	NUMBER OF PATIENTS POSITIVE	# PATIENTS POSTTEST COUNSELED
HIV CTS						
STD						
Drug Treatment						
Family Planning						
Prenatal/OB						
TB						
Other Health Dept						
Prison						
College						
Private MD/Clinic						
Other						
Unknown						
TOTAL						

PROJECT AREA REPORTING

APPROVED BY: TITLE DA

CDC This report is authorized by law (Public Health Service
REV Act, 42 USC 241(a)), and is required as a condition of

APPENDIX C

NATIONAL HEALTH INTERVIEW SURVEY
AIDS KNOWLEDGE AND ATTITUDES SURVEY (STARTED MAY 2, 1988)

OMB# 0920 0214 Approval Expires 3 31 8[illegible]

FORM HIS-4A (1988)

U.S. DEPARTMENT OF COMMERCE
BUREAU OF THE CENSUS
ACTING AS COLLECTING AGENT FOR THE
U.S. PUBLIC HEALTH SERVICE

NATIONAL HEALTH INTERVIEW SURVEY

AIDS KNOWLEDGE AND ATTITUDES

NOTICE – Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated for this study, and will not be disclosed or released to others without the consent of the individual or the establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m).

RT 98

1. 3-7 | 8
Book ____ of ____ books

2. R.O. number 9-10

3. Sample 11-13

4. Control number
PSU 14-16 Segment 17-23 Serial 24-25

5. Beginning time 26-29 30
1 a.m.
2 p.m.

6. NUMBER OF FAMILY MEMBERS 18 + YEARS OLD
(Record number of nondeleted family members 18 + years old.)

______ 31-32

NATIONAL CENTER FOR HEALTH STATISTICS

Revised Questionnaire

Started May2, 1988; expected to be used through the end of 1988. Approximately 800 respondents per week.

7. FINAL STATUS

0 ☐ No person 18 + in this family (Household Page)

Interview (Complete Item 63, Page 18

1 ☐ Complete interview (all appropriate questions completed)

2 ☐ Partial interview (some but not all appropriate questions completed) – *Explain* →

Noninterview (Complete Item 63, Page 18)

3 ☐ Refusal *(Explain in Notes)*
4 ☐ SP temporarily absent
5 ☐ SP mentally or physically incapable
9 ☐ Other – *Explain* →

37

8. Ending time 38-41 42
1 a.m.
2 p.m.

9. Interview mode 43
1 ☐ Personal
2 ☐ Telephone

11. Interviewer identification 44-46
Name
Code

TRANSCRIPTION FROM COMPLETED HIS-1

12. Sex of SP *(Page 2 or 51, question 3)* 47
1 ☐ M
2 ☐ F

13. Education of SP *(Page 42 or 43, question 2a)* 48-49
00 ☐ Never attended or kindergarten
Elem: 1 2 3 4 5 6 7 8
High: 9 10 11 12
College: 1 2 3 4 5 6 +

Finish grade/year *(Question 2b)* 50
1 ☐ Yes
2 ☐ No

14. Main race of SP *(Page 42 or 43, question 3a/b)* 51
1 2 3 4 5 – Specify →

15. Marital status *(Page 46 or 47, question 7)* 52
1 ☐ Married – spouse in HH
2 ☐ Married – spouse not in HH
3 ☐ Widowed
4 ☐ Divorced
5 ☐ Separated
6 ☐ Never married

16. Family income *(Page 46, question 8b)* 53-54
00 ☐ A
01 ☐ B
02 ☐ C
03 ☐ D
04 ☐ E
05 ☐ F
06 ☐ G
07 ☐ H
08 ☐ I
09 ☐ J
10 ☐ K
11 ☐ L
12 ☐ M
13 ☐ N
14 ☐ O
15 ☐ P
16 ☐ Q
17 ☐ R
18 ☐ S
19 ☐ T
20 ☐ U
21 ☐ V
22 ☐ W
23 ☐ X
24 ☐ Y
25 ☐ Z
26 ☐ ZZ

(Transcribe from 8a if 8b blank)
27 ☐ $20,000 or more
28 ☐ Less than $20,000

17. 55-56
Sample Person Number
______

18. 57-58
Sample Person Age
______

19. Booklet type 59
1 = AIDS Knowledge and Attitudes Version 1

PHS-T-570
02-88

Introduction: These next questions are to determine what people know about AIDS, also called Acquired Immunodeficiency Syndrome.

1. In the PAST MONTH, have you . . .		
a. seen any Public Service Announcements about AIDS on television?	1 ☐ Yes 2 ☐ No 9 ☐ DK	60
b. heard any Public Service Announcements about AIDS on the radio?	1 ☐ Yes 2 ☐ No 9 ☐ DK	61
CHECK ITEM 1 — Refer to Q. 1a,b	☐ "Yes" in 1a and/or 1b (2) ☐ Other (3)	
2. Were any of those Public Service Announcements called "America Responds to AIDS"?	1 ☐ Yes 2 ☐ No 9 ☐ DK	62
3. In the PAST MONTH, have you read any brochures or pamphlets about AIDS? Do not include articles in magazines or newpapers.	1 ☐ Yes (5) 2 ☐ No 9 ☐ DK	63
4. Have you EVER read any brochures or pamphlets about AIDS? Again, do not include articles in magazines or newpapers.	1 ☐ Yes (5) 2 ☐ No } (Check Item 2) 9 ☐ DK }	64

5. Where did you get the pamphlets or brochures? Anywhere else? (MARK ALL THAT APPLY)	1 ☐ Clinic, other than work clinic	65
	1 ☐ Doctor's office/HMO	66
	1 ☐ Drug store	67
	1 ☐ Public Health Department	68
	1 ☐ Received it in the mail without asking for it	69
	1 ☐ Red Cross/with Red Cross blood donation	70
	1 ☐ With other blood donation	71
	1 ☐ School	72
	1 ☐ Sent/phoned for it myself, requested it	73
	1 ☐ "The Government" - Federal, state or local	74
	1 ☐ Work, other than clinic or nurse	75
	1 ☐ Work, nurse or clinic	76
	1 ☐ Other (SPECIFY) ____________	77
CHECK ITEM 2 — Refer to assignment	☐ May, June, July (6) ☐ Other (17)	
6. The Government is mailing a brochure with basic information about AIDS to each household in the country. , HOLD COPY UP The brochure looked like this. / The brochure is 8½ by 11 inches, white with blue and black printing, and has a picture of Dr. C. Everett Koop, the Surgeon General of the United States on the cover, with the title, "Understanding AIDS" printed at the top.. Was this brochure received at this household?	1 ☐ Yes (7) 2 ☐ No } (17) 9 ☐ Don't Know } (17)	78
7. How much of the brochure did you read; would you say all or almost all of it, about half, less than half, or none of it?	1 ☐ All/Almost all 2 ☐ About half 3 ☐ Less than half 4 ☐ None } (10) 9 ☐ DK } (10)	79

8. When you read it, did you read it carefully or did you just skim through it?	1 ☐ Read carefully 2 ☐ Skimmed through 8 ☐ Other (SPECIFY) ____________ 9 ☐ DK	80
9. Did the brochure give you any new information or answer any questions you had about AIDS?	1 ☐ Yes 2 ☐ No	81
(IF ONE-PERSON HOUSEHOLD, MARK BOX 3 AND SKIP TO Q. 11) 10. Did you discuss the brochure with anyone else in the family?	1 ☐ Yes 2 ☐ No 3 ☐ One-person	82
11. Do you have any children aged 10 through 17?	1 ☐ Yes 2 ☐ No (21)	83
12. How many do you have?	______	84-85
13. Did [this child/any of your children aged 10 through 17] read the brochure?	1 ☐ Yes 2 ☐ No 9 ☐ DK	86
14. Was the brochure discussed with [this child/any of your children aged 10 through 17]?	1 ☐ Yes (16) 2 ☐ No 9 ☐ DK	87
15. Have you ever discussed AIDS with [this child/any of your children aged 10 through 17]?	1 ☐ Yes 2 ☐ No	88
16. [Has this child/Have any or all of your children aged 10 through 17] had instruction at school about AIDS?	1 ☐ Yes 2 ☐ No 9 ☐ DK } (21)	89
17. Do you have any children aged 10 through 17?	1 ☐ Yes 2 ☐ No (21)	90
18. How many do you have?	______	91-92

19. Have you ever discussed AIDS with [this child/any of your children aged 10 through 17]?	1 ☐ Yes 2 ☐ No	93
20. [Has this child/Have any or all of your children aged 10 through 17] had instruction at school about AIDS?	1 ☐ Yes 2 ☐ No 9 ☐ DK	94
21. How much would you say you know about AIDS --- a lot, some, a little, or nothing?	1 ☐ A lot 2 ☐ Some 3 ☐ A little 4 ☐ Nothing	95
22. To the best of your knowledge, is there a difference between having the AIDS virus and having the disease AIDS?	1 ☐ Yes 2 ☐ No 8 ☐ Other (SPECIFY) ____________________ 9 ☐ DK	96

HAND CARD A

23. After I read each statement, tell me whether you think the statement is definitely true, probably true, probably false, definitely false, or you don't know if it is true or false.

	Def. True	Prob. True	Prob. False	Def. False	DK	
a. AIDS can reduce the body's natural protection against disease.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	97
b. AIDS is especially common in older people.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	98
c. AIDS can damage the brain.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	99
d. AIDS usually leads to heart disease.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	100
e. AIDS is an infectious disease caused by a virus.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	101
f. Teenagers cannot get AIDS.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	102
g. AIDS leads to death.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	103

23. (Continued)

Tell me whether you think each of these statements is definitely true, probably true, probably false, definitely false, or you don't know if it is true or false.

	Def. True	Prob. True	Prob. False	Def. False	DK	
h. A person can be infected with the AIDS virus and not have the disease AIDS.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	104
i. Looking at a person is enough to tell if he or she has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	105
j. ANY person with the AIDS virus can pass it on to someone else through sexual intercourse.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	106
k. A person who has the AIDS virus can look and feel well and healthy.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	107
l. A pregnant woman who has the AIDS virus can give the AIDS virus to her baby.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	108
m. There is a vaccine available to the public that protects a person from getting the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	109
n. There is no cure for AIDS at present.	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	110

HAND CARD B

24. After I read each statement, tell me if you think it is very likely, somewhat likely, somewhat unlikely, very unlikely, definitely not possible, or if you don't know how likely it is that a person will get AIDS or the AIDS virus infection that way.

How likely do you think it is that a person will get AIDS or the AIDS virus infection from ---

	Very likely	Somewhat likely	Somewhat unlikely	Very unlikely	Definitely not possible	DK	
a. living near a home or hospital for AIDS patients.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	111
b. working near someone with the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	112
c. eating in a restaurant where the cook has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	113
d. kissing - with exchange of saliva - a person who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	114
e. shaking hands, touching, or kissing on the cheek someone who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	115
f. sharing plates, forks, or glasses with someone who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	116
g. using public toilets.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	117
h. sharing needles for drug use with someone who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	118
i. being coughed on or sneezed on by someone who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	119
j. attending school with a child who has the AIDS virus.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	120
k. mosquitoes or other insects.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	9 ☐	121

25. Have you ever donated blood?	1 ☐ Yes (26) 2 ☐ No 9 ☐ DK } (27)	122

26. Have you donated blood ---	Yes	No	DK	
a. since March, 1985?	1 ☐	2 ☐ (27)	9 ☐ (27)	123
b. in the past 12 months?	1 ☐	2 ☐	9 ☐	124

27. Have you ever heard of a blood test that can detect the AIDS virus infection?	1 ☐ Yes (28) 2 ☐ No 9 ☐ DK } (44a, Page 12)	125
The next questions are about the blood test for the AIDS virus infection. No question will ask what the results are of any tests you may have had. 28. To the best of your knowledge, are blood donations routinely tested now for the AIDS virus infection?	1 ☐ Yes 2 ☐ No 9 ☐ DK	126
29a. Have you ever received counseling or had a talk with a health professional about taking the AIDS virus test?	1 ☐ Yes (29b) 2 ☐ No 9 ☐ DK } (31)	127

29b. Was the discussion ---	Yes	No	DK	
1. with a private doctor?	1 ☐	2 ☐	9 ☐	128
2. at a family planning clinic?	1 ☐	2 ☐	9 ☐	129
3. on an AIDS hotline?	1 ☐	2 ☐	9 ☐	130
4. at a prenatal clinic?	1 ☐	2 ☐	9 ☐	131
5. at an STD or sexually transmitted disease clinic?	1 ☐	2 ☐	9 ☐	132
6. at an AIDS/HIV counseling and testing site?	1 ☐	2 ☐	9 ☐	133
7. with some other health professional?	1 ☐	2 ☐	9 ☐	134
8. with some other counselor?	1 ☐	2 ☐	9 ☐	135

30. During that discussion, did you receive information about how to avoid getting or passing on the AIDS virus?	1 ☐ Yes 2 ☐ No 9 ☐ DK	136
31. Have you ever been advised by a health professional NOT to have the blood test for the AIDS virus infection?	1 ☐ Yes 2 ☐ No 9 ☐ DK	137
32. Have you ever been advised by friends or relatives NOT to have the blood test for the AIDS virus infection?	1 ☐ Yes 2 ☐ No 9 ☐ DK	138
33. Have you had your blood tested for the AIDS virus infection?	1 ☐ Yes (34a) 2 ☐ No } (41) 9 ☐ DK } (41)	139
34a. Have you had your blood tested for the AIDS virus infection more than once?	1 ☐ Yes (35a) 2 ☐ No 9 ☐ DK	140
34b. Was your blood tested in the past twelve months?	1 ☐ Yes } (36) 2 ☐ No } (36) 9 ☐ DK } (36)	141

35a. How many times have you had your blood tested for the AIDS virus infection?

35b. How many times in the past 12 months have you had your blood tested for the AIDS virus infection?

Total times (35a.)	Number times in past 12 Months (35b.)		142-143 144-145
XXXX	00 ☐	None in past twelve months	
XXXX	01 ☐	One time	
02 ☐	02 ☐	Two times	
03 ☐	03 ☐	Three times	
04 ☐	04 ☐	Four times	
05 ☐	05 ☐	Five times	
06 ☐	06 ☐	Six times	
07 ☐	07 ☐	Seven times	
08 ☐	08 ☐	Eight times	
09 ☐	09 ☐	Nine times	
10 ☐	10 ☐	Ten times	
11 ☐	11 ☐	Eleven times	
12 ☐	12 ☐	Twelve times	
13 ☐	13 ☐	More than twelve times	
99 ☐	99 ☐	DK	

36. ,Was the test --- / Were any of the blood tests, including those you had before the past twelve months ---.		
a. part of a blood donation?	1 ☐ Yes 2 ☐ No	146
b. part of a blood transfusion?	1 ☐ Yes 2 ☐ No	147
c. voluntarily sought from a source such as your doctor, clinic, or HMO?	1 ☐ Yes 2 ☐ No	148
d. part of some other activity that requires a blood sample and includes automatic AIDS testing, such as testing for the military or immigration?	1 ☐ Yes 2 ☐ No	149
CHECK ITEM 3 — Refer to Q. 36d	☐ "Yes" in Q. 36d (37) ☐ Other (38)	
37. Where did you have your blood tested for AIDS virus infection? Anywhere else? (MARK ALL THAT APPLY)	1 ☐ STD clinic	150
	1 ☐ Family planning clinic	151
	1 ☐ Prenatal clinic	152
	1 ☐ Drug treatment facility	153
	1 ☐ Tuberculosis clinic	154
	1 ☐ Work clinic/health station	155
	1 ☐ AIDS counseling/testing site	156
	1 ☐ Military induction	157
	1 ☐ Immigration site	158
	1 ☐ Other (SPECIFY) ________	159
	1 ☐ DK	160
38. Did you get the results of ,your test?/ any of your tests?.	1 ☐ Yes (39) 2 ☐ No } 9 ☐ DK } (40)	161
39. When you received your test results, did you receive counseling or talk with a health professional about how to lower your chances of becoming infected with the AIDS virus or how to avoid passing it to another person?	1 ☐ Yes (41) 2 ☐ No 9 ☐ DK	162

40. Were you referred to a health professional to get counseling about the AIDS virus infection?	1 ☐ Yes 2 ☐ No 9 ☐ DK	163
41. Do you expect to have a blood test for the AIDS virus infection in the next 12 months?	1 ☐ Yes (42) 2 ☐ No } (44) 9 ☐ DK } (44)	164
42. Will you have the blood test ---		
a. as part of a blood donation?	1 ☐ Yes 2 ☐ No 9 ☐ DK	165
b. voluntarily from a source such as your doctor, clinic, or HMO?	1 ☐ Yes 2 ☐ No 9 ☐ DK	166
c. as part of some other activity that requires a blood sample and includes automatic AIDS testing, such as testing for the military or immigration?	1 ☐ Yes 2 ☐ No 9 ☐ DK	167
CHECK ITEM 4 — Refer to Q. 42b	☐ "Yes" In question 42b (43) ☐ Other (44)	
43. Where would you go to have a blood test for the AIDS virus infection? (MARK FIRST MENTION)	00 ☐ Nowhere, wouldn't take the test 01 ☐ AIDS clinic 02 ☐ Company or industry clinic 03 ☐ Doctor/HMO 04 ☐ Hospital/emergency room/OP clinic 05 ☐ Other clinic 06 ☐ Public Health Department 07 ☐ Red Cross/blood bank 88 ☐ Other (SPECIFY) ________ 99 ☐ DK	168-169

44a. Did you have a blood transfusion at any time between 1977 and 1985?	1 ☐ Yes 2 ☐ No 9 ☐ DK	170
44b. Do you think the present supply of blood is safe for transfusions?	1 ☐ Yes 2 ☐ No 9 ☐ DK	171

HAND CARD C

45. Here are some methods people use to keep from getting the AIDS virus through sexual activity.

After I read each one, tell me whether you think it is very effective, somewhat effective, not at all effective, or if you don't know how effective it is in preventing getting the AIDS virus through sexual activity. How effective is ---

	Very effective	Somewhat effective	Not at all effective	DK how effective	DK method	
a. Using a diaphragm?	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	172
b. Using a condom?	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	173
c. Using a spermicidal jelly, foam or cream?	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	174
d. Having a vasectomy?	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	175
e. Two people who do not have the AIDS virus having sex only with each other?	1 ☐	2 ☐	3 ☐	4 ☐	9 ☐	176

46. What are your chances of having the AIDS virus; would you say high, medium, low, or none?	1 ☐ High (Check Item 6) 2 ☐ Medium 3 ☐ Low 4 ☐ None 7 ☐ Refused 9 ☐ DK	177

47.	What are your chances of getting the AIDS virus; would you say high, medium, low, or none?	1 ☐ High 2 ☐ Medium 3 ☐ Low 4 ☐ None 7 ☐ Refused (Check Item 6) 9 ☐ DK	178
48.	People have different meanings when they say a "high", "medium", or "low" chance. If "no chance" is zero-out-of-one hundred, what would you say ,High/Medium/Low. is? What number of times-out-of-one hundred?	000 ☐ Less than 1 out of a 100 ________ out of a 100 999 ☐ DK	179-181
CHECK ITEM 5	Refer to Q. 47	☐ "High" OR "Medium" IN Q. 47 (49) ☐ Other (Check Item 6)	
49.	Do you say your chance of getting AIDS is (high/medium) because you ---		
	a. Have had a blood transfusion?	1 ☐ Yes 2 ☐ No	182
	b. Have had sexual contact with someone who might have the virus?	1 ☐ Yes 2 ☐ No	183
	c. Some other reason? (SPECIFY) ________________ ________________	1 ☐ Yes 2 ☐ No	184

CHECK ITEM 6	Refer to age and sex of S.P.	☐ Female 18-45 (50 Intro, then 50a) ☐ Other (50 Intro, then 50c)

50. In the past twelve months, have you received services or care at ---	Yes	No	DK	
a. a prenatal health clinic?	1 ☐	2 ☐	9 ☐	185
b. a maternal and infant health clinic?	1 ☐	2 ☐	9 ☐	186
c. a family planning clinic?	1 ☐	2 ☐	9 ☐	187
d. a hospital, as an inpatient?	1 ☐	2 ☐	9 ☐	188
e. a hospital emergency room?	1 ☐	2 ☐	9 ☐	189
f. a tuberculosis clinic?	1 ☐	2 ☐	9 ☐	190
g. a drug treatment facility or clinic?	1 ☐	2 ☐	9 ☐	191
h. an STD (sexually transmitted disease) clinic?	1 ☐	2 ☐	9 ☐	192
i. an alcohol treatment facility or clinic?	1 ☐	2 ☐	9 ☐	193
j. an AIDS counseling and testing clinic?	1 ☐	2 ☐	9 ☐	194
k. a community health clinic?	1 ☐	2 ☐	9 ☐	195
l. a public health clinic?	1 ☐	2 ☐	9 ☐	196

51. In the past twelve months, have you ---	Yes	No	DK	
a. been in the Job Corps?	1 ☐	2 ☐	9 ☐	197
b. had a physical examination to join the military?	1 ☐	2 ☐	9 ☐	198
c. been in prison?	1 ☐	2 ☐	9 ☐	199

52. Have you ever discussed AIDS with a friend or relative?	1 ☐ Yes (53) 2 ☐ No } (54) 9 ☐ DK } (54)	200

53. When was the last time you discussed AIDS with a friend or relative?	1 ☐ Today 2 ☐ Days ago 3 ☐ Weeks ago ______ Number 4 ☐ Months ago 5 ☐ Years ago 9 ☐ DK	201-203
54. Have you ever personally known anyone with AIDS or the AIDS virus?	1 ☐ Yes (55) 2 ☐ No } (57) 9 ☐ DK if someone has/had AIDS AIDS virus } (57)	204
(IF MORE THAN ONE PERSON VOLUNTEERED IN Q. 54, ASK Q. 55 and Q. 56 ABOUT THE PERSON KNOWN BEST)		
55. How long has it been since you saw this person?	1 ☐ Within the past two weeks 2 ☐ Two weeks to less than one month 3 ☐ One month to less than 3 months 4 ☐ 3 months to less than 6 months 5 ☐ 6 months or more 9 ☐ DK	205
56. How well do you know this person? Would you say ---	1 ☐ Very well, it is a close relationship? 2 ☐ Fairly well, but it is not a close relationship ? 3 ☐ Not very well, it is only an acquaintance or casual relationship? or 4 ☐ You don't really know them personally, such as a friend of a friend? 8 ☐ Other (SPECIFY) ______________________ ______________________ ______________________	206

HAND CARD D 57. (I am going to read a list of statements. After I have read them all,) Please tell me if any of these statements is true for you. Do not tell me which statement or statements are true for you, just if any of them are. a. You have hemophilia and have received clotting factor concentrates since 1977. b. You are a native of Haiti, Central or East Africa who has entered the United States since 1977. c. You are a man who has had sex with another man at some time since 1977, even one time. d. You have taken illegal drugs by needle at any time since 1977. e. Since 1977, you are or have been the sex partner of any person who would answer "yes" to any of the items (I have read./above on this card.) f. You have had sex for money or drugs at any time since 1977.	207 1 ☐ Yes to at least one statement 2 ☐ No to all statements
58. The U.S.Public Health Service has said that AIDS is one of the major health problems in the country but exactly how many people it affects is not known. The Surgeon General has proposed that a study be conducted and blood samples be taken to help find out how widespread the problem is. If you were selected in this national sample of people to have their blood tested with assurances of privacy of test results, would you have the test?	1 ☐ Yes (60a) 208 2 ☐ No 8 ☐ Other response (SPECIFY) ________________ ________________ ________________ 9 ☐ DK

59. Why wouldn't you take part in the test? Any other reason? (MARK ALL THAT APPLY)	1 ☐ Don't want to know if I have AIDS	(60b)	209
	1 ☐ Don't want any counseling about AIDS		210
	1 ☐ Fear I'll get AIDS	(61)	211
	1 ☐ Don't like to give blood		212
	1 ☐ Don't trust Government programs		213
	1 ☐ It is a waste of money		214
	1 ☐ Don't believe AIDS can really be cured anyway		215
	1 ☐ Other (SPECIFY) ________		216
	1 ☐ DK		217
60a. If it were not possible to provide you with the results of the test, would you still take part in the study?	1 ☐ Yes 2 ☐ No 9 ☐ DK	(61)	218
60b. If the results of the test were not provided to you, then would you take part in the study?	1 ☐ Yes 2 ☐ No 9 ☐ DK		219
61. When Federal Public Health officials give information about AIDS, do you believe what they say or are you doubtful about the information they give?	1 ☐ Believe them 2 ☐ Doubtful 9 ☐ DK		220
62. When they give advice about how to help keep from getting AIDS, do you believe their advice or are you doubtful about what they say?	1 ☐ Believe their advice 2 ☐ Doubtful 9 ☐ DK		221

63. Date AIDS Supplement Final Status _____/_____/19_______ 222-227

INTERVIEWER TRANSCRIPTION FROM HIS-1

64. Hispanic Origin (Item 4a/b, Page 41, HIS-1)

228

HIS-1 Item 4a
1 ☐ Yes
2 ☐ No

229

HIS 1 Item 4b
1 ☐ Puerto Rican
2 ☐ Cuban
3 ☐ Mexican/Mexicano
4 ☐ Mexican American
5 ☐ Chicano
6 ☐ Other Latin American
7 ☐ Other Spanish

65. Questionnaire Version 1 230

RT 99

66. Exact Address (Item 6a, Cover Page, HIS-1)

____

____ 28-93

____ 94-114
City State County ZIP Code 115-116
117-142
143-151

67. Mailing Address (Item 6b, Cover Page, HIS-1)

☐ Same as 6a 152

____

____ 153-206

____ 209-229
City State County ZIP Code 230-231
232-257
258-266

68. Telephone Number (Item 11, Cover Page, HIS-1)

267

1 ☐ Yes, telephone (RECORD NUMBER BELOW)
2 ☐ No telephone
3 ☐ Phone, but no number listed or number refused
9 ☐ DK or Refused

_____/_____/__________ 268-277
A.C. Exch. Number

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